NOVOSTE CORP /FL/
Form 10-Q
November 04, 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 September 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	**59-2787476**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

3890 Steve Reynolds Blvd. Norcross, GA	**30093**
(Address of Principal Executive Offices)	**(Zip Code)**

(770) 717-0904

(Registrant s telephone, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such requirements for the past 90 days.

(Item 1) Yes x No ¨

(Item 2) Yes x No ¨

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

As of October 29, 2003 there were 16,318,213 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)

	September 30, 2003	December 31, 2002
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,302	$ 21,928
Short-term investments	6,362	11,647
Accounts receivable, net of allowance of $463 and $1,135 respectively	6,069	6,758
Inventory, net	3,388	3,927
Prepaid expenses and other current assets	548	986
Total current assets	47,669	45,246
Property and equipment, net	7,834	9,542
Radiation and transfer devices, net	7,088	11,353
Receivable from officers		283
Other assets	610	1,096
	$ 63,201	$ 67,520
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,007	$ 2,176
Accrued expenses	6,521	9,967
Unearned revenue	169	2,429
Capital lease obligations	13	178
Total current liabilities	7,710	14,750
Long-term liabilities		
Capital lease obligations		5
Total liabilities	7,710	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; 16,360,142 and 16,351,953 shares issued, respectively	164	164
Additional paid-in capital	187,782	187,813
Accumulated other comprehensive income	448	190
Accumulated deficit	(132,665)	(134,434)
	55,729	53,733

Less: Treasury stock, 42,929 and 118,077 shares of common stock at cost	(172)	(445)
Unearned compensation	(66)	(523)
Total shareholders equity	55,491	52,765
	$ 63,201	$ 67,520

See accompanying notes.

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NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per-share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net sales	$ 13,531	$ 14,655	$ 51,845	$ 54,412
Cost of sales	5,535	6,774	18,921	19,667
Impairment charge				6,900
Gross margin	7,996	7,881	32,924	27,845
Operating expenses:				
Research and development	3,198	3,501	9,362	9,624
Sales and marketing	4,496	5,851	15,577	20,614
General and administrative	1,856	1,910	6,421	6,508
Total operating expenses	9,550	11,262	31,360	36,746
Income (loss) from operations	(1,554)	(3,381)	1,564	(8,901)
Interest income	40	107	223	621
Interest expense	(5)	(13)	(14)	(100)
Other income (expense)			5	(6)
Total other income	35	94	214	515
Income (loss) before taxes	(1,519)	(3,287)	1,778	(8,386)
Income taxes			8	50
Net income (loss)	$ (1,519)	$ (3,287)	$ 1,770	$ (8,436)
Net income (loss) per share - Basic	$ (0.09)	$ (0.20)	$ 0.11	$ (0.52)
Weighted average shares outstanding - Basic	16,343	16,286	16,311	16,293
Net income (loss) per share - Diluted	$ (0.09)	$ (0.20)	$ 0.11	$ (0.52)
Weighted average shares outstanding - Diluted	16,343	16,286	16,743	16,293

See accompanying notes.

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NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine Months Ended September 30,	
	2003	**2002**
Cash flows from operating activities:		
Net income (loss)	$ 1,770	$ (8,436)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,629	1,860
Issuance (cancellation) of stock options for services or compensation	(87)	197
Amortization of deferred compensation	173	139
Amortization of radiation and transfer devices	6,984	4,994
Provision for doubtful accounts	(318)	230
Changes in assets and liabilities:		
Accounts receivable	1,054	6,695
Inventory	551	(111)
Prepaid expenses	438	142
Accounts payable	(1,209)	(1,431)
Accrued expenses	(3,469)	(1,731)
Unearned revenue	(2,271)	(1,215)
Impairment charge		5,065
Other	835	(307)
Net cash provided by operating activities	7,080	6,091
Cash flows from investing activities:		
Maturity/sale of short-term investments	14,556	31,005
Purchase of short-term investments	(9,271)	(14,573)
Purchase of property and equipment, net	(906)	(2,164)
Purchase of radiation and transfer devices	(2,719)	(8,231)
Net cash provided by investing activities	1,660	6,037
Cash flows from financing activities:		
Proceeds from issuance of common stock	721	468
Purchase of treasury stock	(110)	(616)
Repayment of capital lease obligations	(169)	(199)
Net cash provided by financing activities	442	(347)
Effect of exchange rate changes on cash	192	460
Net increase in cash and cash equivalents	9,374	12,241
Cash and equivalents at beginning of period	21,928	5,878
Cash and cash equivalents at end of period	$ 31,302	$ 18,119
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ (14)	$ (97)

See accompanying notes.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 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 unaudited 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.

Novoste sells its catheters with no right of return except in cases of product malfunction or shipping errors. In connection with the re-launch, Novoste exchanged 5.0F catheters for 3.5F catheters with a number of its customers. In earlier periods, a reserve was recorded against revenue for known returns and an estimate of unknown returns. The exchange of these catheters was completed by September 2003 and all related reserves have been eliminated. 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 September 30, 2003 were positively impacted by the reduction of $0.4 million in the revenue reserve for 5.0F catheters that were replaced with the new 3.5F catheters during the third quarter. (See also Notes 6 and 12 to unaudited consolidated financial statements.)

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 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.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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(continued)

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

	Three Months Ended September 30 (unaudited)		Nine Months Ended September 30 (unaudited)	
	2003	2002	2003	2002
Net income (loss), as reported	$ (1,519)	$ (3,287)	$ 1,770	$ (8,436)
Add: Total stock-based employee compensation expense included in reported net income (loss)	15	43	87	336
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(826)	(1,545)	(3,106)	(4,681)
Pro forma net loss	$ (2,330)	$ (4,789)	$ (1,249)	$ (12,781)
Earnings (loss) per share:				
Basic-as reported	$ (0.09)	$ (0.20)	$ 0.11	$ (0.52)
Basic-pro forma	$ (0.14)	$ (0.29)	$ (0.08)	$ (0.78)
Diluted-as reported	$ (0.09)	$ (0.20)	$ 0.11	$ (0.52)
Diluted-pro forma	$ (0.14)	$ (0.29)	$ (0.08)	$ (0.78)

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

interim financial periods beginning after June 15, 2003. There is no impact of FIN 46 on our results of operations.

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 has not had any impact on our results of operations or financial position.

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.

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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(continued)

NOTE 4. ACCOUNTS RECEIVABLE

Accounts receivable at September 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 September 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 September 30, 2003 was $63,000 as compared to bad debt expense of $166,000 in the three-month period ended September 30, 2002. For the nine-month period ended September 30, 2003 bad debt recovery was a net of $340,000, as compared to bad debt expense of $330,000 in the nine-month period ended September 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):

	September 30, 2003	December 31, 2002
Raw Materials	$ 2,271	$ 2,878
Work in Process	182	202
Finished Goods	935	847
Total	$ 3,388	$ 3,927

Inventory reserves decreased from $844,000 at December 31, 2002 to $581,000 at September 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. Novoste classifies the annual agreements with Novoste s customers to license the use of radiation and transfer devices as operating leases. Income is recognized ratably over the length of the lease. At September 30, 2003, deferred revenue under these leases approximated $169,000.

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

	September 30, 2003	December 31, 2002
Radiation and Transfer Devices	$ 32,374	$ 31,005
Less: Impairment	(5,065)	(5,065)
Net Radiation and Transfer Devices	27,309	25,940
Less: Accumulated Depreciation	(20,221)	(14,587)
	$ 7,088	$ 11,353

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.

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SEPTEMBER 30, 2003

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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) the time required to complete training on the new 3.5F catheter replacement systems, and (c) allocations of 3.5F catheter systems to customer sites based on availability, customer preference and volume potential. Taking these factors into account in our quarterly review of the accuracy of our estimates, and after extensive market review and technology assessment, Novoste concluded that the 5.0F catheter assets will most likely remain in active use through December 31, 2003. Accordingly, the remaining value of the 5.0F catheter assets will be amortized through December 31, 2003, rather than through March 31, 2003, as previously estimated. The result of this change in the estimated useful life reduced amortization expense in the first quarter of 2003 by $1,237,000, and increased amortization expense by $413,000 for subsequent quarters in 2003.

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

	Nine Months Ended
Impact	**September 30, 2003**
Decrease in Cost of Sales	$ 411
Increase in income per share - basic	$ 0.03
Increase in income per share - diluted	$ 0.02

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 September 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 September 30, 2003, Novoste had no outstanding borrowings. Novoste may borrow an amount not to exceed the borrowing base as defined in the loan agreement, which is principally based on domestic accounts receivable. Interest on outstanding balances is payable on the first of each month, calculated on the outstanding balance, 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 to February 27, 2004. Also as part of that modification, the tangible net worth covenant was changed, bringing Novoste into compliance, and the interest rate was changed to a base of the greater of the bank s prime rate, or 4.25%, plus 1%.

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

Net sales

	United States	Rest of World	Consolidated
2003	$ 48,235	$ 3,610	$ 51,845
2002	50,833	3,579	54,412

Net income (loss)

	United States	Rest of World	Consolidated
2003	$ 1,920	$ (150)	$ 1,770
2002	(5,668)	(2,768)	(8,436)

Long-lived assets

	United States	Rest of World	Consolidated

2003	$ 14,516	$ 406	$ 14,922
2002	19,389	2,509	21,898

Total assets

	United States	Rest of World	Consolidated
2003	$ 59,381	$ 3,820	$ 63,201
2002	64,918	5,623	70,541

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 nine months ended September 30, 2003, stock options representing approximately 1.2 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 nine-month period (2.8 million shares were excluded in the nine months ended September 30, 2002 as they were anti-dilutive). These options could be dilutive in the future if there is an increase in the price of Novoste common stock.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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(continued)

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2003	2002	2003	2002
Numerator:				
Net income (loss)	$ (1,519)	$ (3,287)	$ 1,770	$ (8,436)
Denominator:				
Weighted-average shares outstanding	16,343	16,286	16,311	16,293
Dilutive effect of stock options and unvested restricted stock			432	
Weighted-average shares outstanding, assuming dilution	16,343	16,286	16,743	16,293
Net income (loss) per share:				
Basic	$ (0.09)	$ (0.20)	$ 0.11	$ (0.52)
Diluted	$ (0.09)	$ (0.20)	$ 0.11	$ (0.52)

NOTE 11. SHAREHOLDERS EQUITY

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2003	2002	2003	2002
Shareholders equity at beginning of period	$ 57,018	$ 61,014	$ 52,765	$ 64,728
Proceeds from exercise of stock options ranging from $1.00 to $6.65 per share	4		659	364
Proceeds from Employee Stock Purchase Plan at $5.82 per share on 6/30/03 and $4.08 per share on 6/28/02			62	104
Amortization of unearned compensation	28	42	111	682
Stock re-purchase of 25,600 and 159,800 shares in 2003 and 2002, respectively	(110)	(616)	(110)	(616)
Deferred compensation related to accelerated vesting of certain stock options				197

Revaluation of Variable Stock Awards	(6)		(13)	
Cancellation of unvested Restricted Stock Awards	(7)		(11)	(543)
Comprehensive income:				
Unrealized gain on held-for-sale securities	33	(6)	19	(6)
Translation adjustment	50	(213)	239	460
Net income/(loss)	(1,519)	(3,287)	1,770	(8,436)
Total comprehensive income/(loss)	(1,436)	(3,506)	2,028	(7,982)
Shareholders equity at end of period	$ 55,491	$ 56,934	$ 55,491	$ 56,934

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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(continued)

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.

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. Following the re-launch of a redesigned 3.5F catheter system in January, 2003, the 5.0F systems continued to be utilized, but at a declining rate as 3.5F systems returned to use. The revenue of the 5.0F systems has continued to exceed carrying value and Novoste has concluded that these assets will likely remain in active use through December 31, 2003. At September 30, 2003, approximately $0.4 million of unamortized costs remain for the 5.0F impaired assets.

NOTE 13: TERMINATION COSTS

Eighty-seven employees located in the U.S. were terminated during the nine months ended September 30, 2003, to align Novoste s staffing with current market conditions. Termination costs of $565,000 and $761,000 were recorded in the three and nine-months ended September 30, 2003,

respectively. $504,000 and $700,000 were paid in the three and nine-months ended September 30, 2003, respectively. These costs are included in operating expense in the consolidated statement of operations for the periods concerned.

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

The forward-looking statements in this Form 10-Q are made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended. Our operating results and financial condition have varied and may in the future vary significantly depending on a number of factors. Statements in this Form 10-Q which are not strictly historical statements, including, without limitation, statements regarding management s expectations for future growth and plans and objectives for future management and operations, domestic and international marketing and sales plans, product plans and performance, research and development plans, management s assessment of market factors, as well as statements regarding our strategy and plans, constitute forward-looking

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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 negative of these words or comparable words. The factors listed under Cer 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.

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

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

Novoste retains ownership of the radiation source trains and transfer devices and enters into either a lease or license agreement with its customers. Revenue recognition begins once an agreement has been executed, the system has been 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 was recorded against revenue for known returns and an estimate of unknown returns. The exchange of these catheters was completed by September 2003.

Radiation and Transfer Devices and Amortization of Costs

Novoste retains ownership of the RSTs and TDs that are leased to customers. The costs to acquire, test and assemble these assets are recorded as incurred. Novoste has determined that based upon 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.

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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 could 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 and 12 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 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 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 subsequent quarters. (See Note 6 and 12 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.

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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.

RESULTS OF OPERATIONS

Net loss for the third quarter 2003 decreased to $1,519,000 or $0.09 per share, basic and diluted, as compared to a net loss of $3,287,000 or $0.20 per share, basic and diluted, for the third quarter of 2002. Net income increased to $1,770,000 or $0.11 per share, basic and diluted, as compared to a net loss of $8,436,000 or $0.52 per share, basic and diluted, for the nine months ended September 30, 2002.

Results for the third quarter 2003 were negatively affected by lower revenues which were impacted by the introduction of drug-eluting stents (DES), the third quarter 2003 being the first full quarter of their market release. The resulting decline in income was offset by cost reduction initiatives (See Note 13 to the unaudited consolidated financial statements). Income in the third quarter 2003 was positively affected by $360,000 due to recognition of revenue previously deferred in connection with catheter exchanges. Year-to-date results improved over last year due to lower operating costs, the turn-around in European operations and the absence of last year s impairment charge of $6,900,000 during the second quarter of 2002.

Net Sales. Net sales decreased 8% to $13,531,000 and decreased 5% to $51,845,000 in the three and nine months ended September 30, 2003, respectively, as compared to net sales of $14,655,000 and $54,412,000 for the three and nine months ended September 30, 2002, respectively. Net sales recorded in the United States decreased 12% to $12,353,000 and decreased 5% to $48,235,000 in the three and nine months ended September 30, 2003, respectively, as compared to net sales of $14,007,000 and $50,833,000 for the three and nine months ended September 30, 2002, respectively. Comparatively, international net sales for the three and nine months ended September 30, 2003 increased 82% to $1,178,000 and 1% to $3,610,000, respectively, as compared to net sales of $648,000 and $3,579,000 for the three and nine months ended September 30, 2002, respectively.

Net sales decreased 8% in the third quarter 2003 from the same quarter in the prior year. Catheter revenue in the third quarter 2003 was positively impacted by reducing the reserve for future catheter exchanges by $400,000. Excluding revenue reserves in both the current and prior year s third quarter, catheter sales for the third quarter 2003 declined 6% from prior year levels. We believe that this decline was due to the launch of drug-eluting stents and the resulting increased competition. Lease revenue declined 76% due to competitive pressure to renew the

radiation device leases at considerably lower prices. The 82% increase over the same quarter last year in international sales is a combination of $170,000 in revenue from stents, a product line first licensed for sale by Novoste earlier in 2003, and a rebound from lower international sales in the third quarter last year which were adversely affected by the recall of 3.5F diameter catheters.

Net sales for the nine months ended September 30, 2003 declined 5% compared to the same period in 2002. Catheter revenue increased by 1%. This increase in the nine months ended September 30, 2003 compared to the same period last year, can be attributed to the recognition of revenue deferred in anticipation of catheter exchanges for product sold before December 31, 2002. (See Note 1 to unaudited consolidated financial statements). Without this recognition, catheter revenue declined 5% from the prior year. Novoste believes this decrease was due to the launch of drug-eluting stents starting in the second quarter of 2003 along with intense competition in this market segment. Lease revenue declined 77% due to lease renewals at nominal cost to the customers.

Cost of Sales. Cost of sales decreased 18% to $5,535,000 and 4% to $18,921,000 in the three and nine months ended September 30, 2003, with the gross margin of $7,996,000, or 59% of revenue, and $32,924,000 or 64% of revenue, respectively. Cost of sales were $6,774,000 and $19,667,000 for the three and nine months ended September 30, 2002, with the gross margin of $7,881,000, or 54% of revenue and $27,845,000, or 51% of revenue, respectively.

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In the quarter ended September 30, 2003, gross margin increased approximately $115,000 compared to the quarter ended September 30, 2002, as a result of the recognition of deferred revenue and lower manufacturing costs. Last year s third quarter gross margin was negatively impacted by the *Beta-Rail* 3.5F delivery catheter voluntary recall and related costs.

On a year-to-date basis, excluding the impairment charge of $6.9 million in 2002, gross margin declined $1,821,000 in the nine-month period ended September 30, 2003 due to lower lease revenue, and additional amortization expense. (See Note 6 and 12 to the unaudited consolidated financial statements).

We believe significant factors impacting cost of sales and gross margins in the fourth quarter of 2003 will include the utilization of catheters at the sites using the Beta-Cath System, the additional costs to service the two sizes of catheter systems and amortization of radiation devices used in the field. With the re-launch of the redesigned 3.5F in January 2003, Novoste is pursuing its strategy of going to a single vascular brachytherapy (VBT) system with the goal of lowering costs as maintenance of a second catheter system is eliminated.

Research and Development Expenses. Research and development expenses decreased 9% to $3,198,000 for the three months ended September 30, 2003, from $3,501,000 for the three months ended September 30, 2002. Research and development expenses decreased 3% to $9,362,000 for the nine months ended September 30, 2003, from $9,624,000 for the nine months ended September 30, 2002.

The decrease in the three-months ended September 30, 2003 compared to prior year was primarily in the area of clinical trials with the suspension of the MOBILE (More Beta Radiation In Lower Extremities) trial. Future research and development efforts will be focused on the BRAVO II trial, which is designed to study the clinical effect of vascular brachytherapy in preventing arterio-venous grafts from occluding.

The decrease in research and development expenses for the nine-month period in 2003 compared to the prior year is due to reduced activity levels for the MOBILE trial and a slower enrollment rate for the BRAVO II trial.

Sales and Marketing Expenses. Sales and marketing expenses decreased 23% to $4,496,000 for the three months ended September 30, 2003, from $5,851,000 for the three months ended September 30, 2002. Sales and marketing expenses decreased 24% to $15,577,000 for the nine months ended September 30, 2003, from $20,614,000 for the nine months ended September 30, 2002.

The decrease in the three-month period in 2003 compared to prior year is due to reduced sales and marketing personnel (See Note 13 to the unaudited consolidated financial statements) and lower variable selling expenses related to lower revenues.

The decrease in the nine-month period in 2003 compared to the prior year is due mainly to lower variable selling expenses related to lower revenues. Other factors leading to reduced costs include lower expenses in Europe due to the closure of the Belgian office in early 2002, reduced sales and marketing personnel, and lower marketing expenses due to our participation in fewer tradeshows and promotional activities in a mature marketplace compared to the previous year. Last year, we introduced the 3.5F diameter catheter in March 2002 and incurred expenses associated with such introduction in the nine-month period in 2002. We did not incur such expenses in the same period in 2003.

General and Administrative Expenses. General and administrative expenses decreased 3% to $1,856,000 for the three months ended September 30, 2003, from $1,910,000 for the three months ended September 30, 2002. General and administrative expenses decreased 1% to $6,421,000 for the nine months ended September 30, 2003, from $6,508,000 for the nine months ended September 30, 2002.

The decline for the three-month period in 2003 compared to the prior year is due to the completion of a computer systems upgrade project and continued efforts at cost reduction.

The decrease for the nine-month period in 2003 compared to the prior year is due to ongoing efforts in cost reduction in 2003, along with productivity improvements that require less resources.

Other Income and Expenses. Other income decreased 63% to $35,000 for the three months ended September 30, 2003, from $94,000 for the three months ended September 30, 2002. Other income decreased 58% to $214,000 for the nine months ended September 30, 2003, from $515,000 for the nine months ended September 30, 2002.

This decrease for the three month period in 2003 compared to the prior year is mainly due to the lower interest rate environment for short-term investments. Net interest income is down 63% from the same quarter last year.

This decrease in Other Income and Expenses for the nine-month period ended September 30, 2003 compared to the prior year is due to lower interest rates and zero borrowings resulting in $398,000 of less interest income offset by $86,000 of reduced interest expense.

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LIQUIDITY AND CAPITAL RESOURCES

Operating

Net cash provided by operating activities was $7,080,000 for the nine months ended September 30, 2003, compared to $6,091,000 in the prior year period.

Cash resulting from depreciation and amortization charges was $9,613,000 for the nine months ended September 30, 2003, compared to $6,854,000 for the same period in 2002 on a smaller investment base. The decline in receivables generated $1,054,000 and $6,695,000 in cash for the nine months ended September 30, 2003 and 2002, respectively, due to lower sales volume and proactive collection efforts. Payables and accruals have declined, requiring funds of $4,678,000 and $3,162,000 for 2003 and 2002, respectively. Unearned revenue declined as leases on equipment have matured and revenue reserves associated with the catheter exchange (See Note 1, to the unaudited consolidated financial statements) have been eliminated.

Investing

Novoste s capital purchases have declined. Investments have shifted to cash equivalents to provide flexibility for future strategic investments. For the nine months ended September 30, 2003 net investment liquidation exceeded capital investment by $1,660,000 compared to $6,037,000 for the prior year.

Novoste s shift in its investments toward cash equivalents lowered average short-term investments by 55% at the end of the third quarter of 2003 as compared to the third quarter of 2002. Less cash was used to purchase property and equipment in the nine months ended September 30, 2003 as compared to the same period of 2002 by $1,258,000, primarily due to the completion of the production facility for radiation source trains in September 2002. Less cash was used to purchase radiation source trains and transfer devices in the same periods by $5,512,000. This decrease in cash used to purchase transfer devices in the nine months ended September 30, 2003 reflects the deployment of devices to most of the sites using VBT, and fewer new sites in 2003. The maturity of the coronary VBT market segment reduces the need for new transfer devices. Novoste anticipates that the purchase of radiation source trains and transfer devices will continue at a slower rate, as Novoste completes conversion of customer 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 September 30, 2003, Novoste issued 1,000 shares of its common stock at an average price of $3.64 as various employee stock options were exercised.

In August 2003, Novoste announced the extension of the stock buy-back program originally begun in August 2002, but suspended due to the 3.5F catheter recall. The extension authorized the purchase of up to $7 million.

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 September 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 September 30, 2003, Novoste had no outstanding letters of credit.

Commitments

At September 30, 2003, Novoste had commitments to purchase $2.5 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 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.

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

Novoste has entered into a license agreement with a physician pursuant to which he is entitled to receive a royalty on the net sales of the Beta-Cath System (excluding consideration paid for the radioactive isotope), subject to a maximum aggregate payment of $5,000,000. Royalty fees paid to the physician were $126,000 and $133,000 for the three months ended September 30, 2003 and 2002, respectively, and $483,000 and $511,000 for the nine months ended September 30 2003 and 2002, respectively, and have been expensed in cost of sales. As of September 30, 2003, aggregate payments of $1,854,000 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 $254,000 and $269,000 for the three months ended September 30, 2003 and 2002, respectively, and $983,000 and $1,064,000 for the nine months ended September 30, 2003 and 2002 respectively, and have been expensed in cost of sales.

Liquidity

Novoste s principal source of liquidity at September 30, 2003 consisted of cash, cash equivalents and short-term investments of $37.7 million compared to $33.6 million at September 30, 2002.

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

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 2004.

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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 Information 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 nine 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 86% of all PTCA procedures performed in the U.S. in 2002. 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.

Guidant, and to a lesser extent, Johnson & Johnson, 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

restenosis rates to below 10%. In addition, Johnson & Johnson received FDA approval in April 2003 and has established a significant commercial market for its drug-eluting stent in the U.S. This has had and may continue to have an adverse effect on Novoste s business.

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

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

Like other firms that engage in the development of medical devices, we must address issues and risks relating to patents and trade secrets. United States Patent No. 5,683,345 may not offer adequate protection to us because competitors may be able to design

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

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

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

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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 assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

Our Quarterly Operating Results May Vary

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

We Are Highly Dependent On Key Personnel

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

Our Lack Of Redundant Manufacturing Facilities Could Harm Our Business

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

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

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

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

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

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

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

Item 3. Quantitative And Qualitative Disclosures About Market Risk

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

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

Interest Rate Risk

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

At September 30, 2003, Novoste had $31.3 million in cash equivalents with a weighted average interest rate of 0.702% and $6.4 million in available-for-sale investments with a weighted average interest rate of 1.170%.

Foreign Currency Risk

International revenues from Novoste s foreign direct sales and distributor sales comprised 9% and 4% of total revenues for the three month periods ended September 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 September 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 September 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.

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 in our quarterly report for the quarter ended June 30, 2003, filed with the Securities and Exchange Commission, we are not aware of any such assertions that would have a material effect on Novoste.

On October 6, 2003, Novoste commenced litigation against Scott Sacane, Durus Capital Management, LLC, and Durus Life Sciences Master Fund, Ltd., in the United States District Court for the District of Connecticut. The suit was filed as a result of information disclosed in Securities and Exchange Commission filings by Scott Sacane and Durus Capital Management, LLC, which indicated that the Durus Life Sciences Master Fund, Ltd. had, in October 2002, become a greater than ten percent (10%) shareholder of Novoste and had, subsequently, under the direction of Scott Sacane and Durus Capital Management, LLC, purchased and sold and sold and purchased shares of Novoste Common Stock during periods of less than six months. The law suit seeks recovery of the profits made by the defendants from purchases and sales of Novoste Common Stock that represent short-swing transactions under Section 16(b) of the Securities Exchange Act of 1934, attorney s fees and such other relief as the court deems proper.

Item 2. Changes in Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

None.

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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(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
	31.2	Certification of Subhash C. Sarda, Acting Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
	32.1	Statements of Alfred J. Novak, Chief Executive Officer, and Subhash C. Sarda, Acting Chief Financial Officer, pursuant to 18 U.S.C. Section 1350.*

(1) Filed as same numbered Exhibit to the Registrant s Report on Form 10-K filed on March 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).
(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 no reports on Form 8-K filed by Novoste during the quarter ended September 30, 2003.

Subsequent Form 8-K Filing

On October 22, 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 September 30, 2003. A copy of the release was furnished as an exhibit pursuant to Item 12 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

November 4, 2003

Date