NOVOSTE CORP /FL/
Form 10-Q
November 14, 2002

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, 2002

[ ] 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

As of October 31, 2002 there were 16,186,373 shares of the Registrant's Common Stock outstanding.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NOVOSTE CORPORATION
CONSOLIDATED BALANCE SHEETS

	September 30, 2002 (Unaudited)	December 31
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,119,111	$ 5,878
Short-term investments	15,251,150	31,683
Accounts receivable, net of allowance of $1,108,892 and $878,424 respectively	9,205,583	16,130
Inventory, net	3,857,748	3,746
Prepaid expenses and other current assets	881,217	1,023
Total current assets	47,314,809	58,462
Property and equipment, net	10,190,613	9,886
Radiation and transfer devices, net	11,706,885	13,534
Receivable from officers	279,829	144
Other assets	1,048,818	883
Total assets	$ 70,540,954	$ 82,910
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,596,320	$ 4,026
Accrued expenses	9,186,296	10,917
Unearned revenue	1,571,624	2,786
Capital lease obligations	69,986	249
Total current liabilities	13,424,226	17,979
Long-term liabilities		
Capital lease obligations	182,852	203
Shareholders' equity:		
Preferred stock, $.01 par value, 5,000,000 shares authorized; no shares issued and outstanding	-	
Common stock, $.01 par value, 25,000,000 shares authorized; 16,351,953 and 16,265,081 shares issued,	163,520	162
Additional paid-in capital	187,478,589	187,357
Accumulated other comprehensive income (loss)	51,464	(408
Accumulated deficit	(129,819,404)	(121,383
	57,874,169	65,728
Less treasury stock, 165,580 and 5,780 shares of common stock at cost	(639,870)	(23
Unrealized loss on Held-for-Sale Securities	(6,000)	
Unearned compensation	(294,423)	(976
Total shareholders' equity	56,933,876	64,727
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 70,540,954	$ 82,910

See accompanying notes.

NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		
	2002	2001	200
Net sales	$ 14,655,449	$ 20,916,639	$ 54
Cost of sales	6,774,235	5,118,949	19
Impairment charge	-	-	6
Gross margin	7,881,214	15,797,690	27
Operating expenses:			
Research and development	3,501,473	2,941,372	9
Sales and marketing	5,850,804	8,990,636	20
General administrative	1,909,597	2,252,761	6
Total operating expenses	11,261,874	14,184,769	36
Income (loss) from operations	(3,380,660)	1,612,921	(8
Interest income, interest expense and other, net	93,786	473,320	
Income (loss) before income taxes	(3,286,874)	2,086,241	(8
Income taxes	-	-	
Net income (loss)	$ (3,286,874)	$ 2,086,241	$ (8
Net income (loss) per share - Basic	$ (0.20)	$ 0.13	$
Weighted average shares outstanding Basic	16,286,445	16,188,275	16
Net income (loss) per share - Diluted	$ (0.20)	$ 0.13	$
Weighted average shares outstanding Diluted	16,286,445	16,418,391	16

See accompanying notes.

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NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

	For The Nine Months September 30, 2002	2
Cash flows from operating activities:		
Net loss	$(8,435,877)	$ (
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	1,860,043	
Issuance (cancellation) of stock for service or compensation	196,875	
Amortization of deferred compensation	139,268	
Amortization of radiation & transfer devices	4,993,786	
Provision for doubtful accounts	230,468	
Non-cash impairment Charge	5,065,000	
Changes in assets and liabilities:		
Accounts receivable	6,694,670	(1
Inventory	(111,315)	(
Prepaid expenses	141,920	
Accounts payable	(1,430,546)	
Accrued expenses and taxes withheld	(1,730,982)	
Unearned revenue	(1,214,852)	
Other	307,311	
Net cash generated (used) by operations	6,091,149	(
Cash flow from investing activities:		
Maturity (purchase) of short-term investments	16,432,477	
Purchase of property and equipment, net	(2,163,945)	(
Purchase of radiation and transfer devices	(8,231,315)	(
Net cash provided by (used by) investing activities	6,037,217	(
Cash flows from financing activities:		
Proceeds from issuance of common stock	468,397	
Purchase of Treasury Stock	(616,030)	
Repayment of capital lease obligations	(199,509)	
Net cash provided (used) by financing activities	(347,142)	
Effect of exchange rate changes on cash	459,602	
Net increase (decrease) in cash and cash equivalents	12,240,825	(1
Cash and equivalents at beginning of period	5,878,286	2
Cash and cash equivalents at end of period	$18,119,111	$ 1
SUPPLEMENTAL DISCLOSURE OF CASH FLOW Information:		
Cash paid for interest	(97,331)	
Non-cash investing and financing activities:		
Assets acquired under capital lease		

See accompanying notes.

NOVOSTE CORPORATION
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2002

NOTE 1. BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles 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, 2002. The accompanying consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2001 included in the Company's 2001 Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC").

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 July, 2002. Significant inter-company transactions and accounts have been eliminated.

On August 19, 2002, the Company initiated a voluntary recall of the Beta-Rail(TM) 3.5F Delivery Catheter inventory from its customers. The recall related to the discovery by the Company of a small number of catheter-tip separations in the 3.5F 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, defining the improvements to the product and manufacturing processes and requesting approval for re-launch of the product. The FDA has one hundred and eighty (180) days to act on the PMA supplement with an approval or a denial to re-launch the product. Additionally, the FDA may require additional information from the Company prior to acting on the application.

The impact of the 3.5F catheter recall has been included in the consolidated financial statements of the Company and is recorded in the corresponding revenue and expense categories as appropriate based upon the nature of the expense or adjustment. Net sales were adjusted by approximately $3.0 million for 3.5F catheters that were sold to customers but subsequently returned due to the recall. Cost of sales reflects approximately $800,000 for the disposal of existing 3.5F catheters in inventory and for the additional labor and costs in

shipping 5.0F transfer devices, radiation source trains and catheters to our customers. Operating expenses reflect the labor and material costs involved in testing the 3.5F catheters in order to determine the proper corrective actions to be included in our reports to the FDA.

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. 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, the Company has investments in commercial paper and other securities that are classified as short-term. Management determines the appropriate classification of debt securities at the time of purchase.

All securities are considered as available-for-sale and reported at fair value, with the unrealized gains and losses reported in a separate component of shareholders' equity, if significant. 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 are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income. At September 30, 2002, fair value approximated net book value for all short-term investments and all were considered available-for-sale and have been accounted for as such.

NOTE 3. ACCOUNTS RECEIVABLE

Accounts receivable at September 30, 2002 and December 31, 2001 include receivables due from product sales and amounts due under lease arrangements relating to radiation and transfer devices (see Note 5. Radiation and Transfer Devices). The carrying amounts reported in the consolidated balance sheets for accounts receivable approximate their fair value. The Company 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.

During the quarter Novoste recalled all 3.5F diameter catheters (see Note 1). The returned catheters generated credits of approximately $3 million to customers who could use the value of the credits in a variety of ways, including the purchase of replacement 5F catheters, the clearing of existing obligations, the application of the value against future purchases, or the customer could request a cash refund.

Accounts receivable at September 30, 2002 have been adjusted to reflect all credits associated with the recall on customers with invoices outstanding. The remaining credits for customers with no invoices outstanding have been classified as accrued liabilities.

Bad debt expense for the three-month periods ended September 30, 2002 and 2001 amounted to $165,572 and $290,000, respectively, and for the nine-month periods ended September 30, 2002 and 2001 were $329,680 and $590,000.

NOTE 4. 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:

	September 30, 2002	December 31, 2001
Raw Materials	$ 3,091,199	$ 1,971,347
Work in Process	265,715	811,406
Finished Goods	508,834	963,680
Total	$ 3,857,748	$ 3,746,433

NOTE 5. RADIATION AND TRANSFER DEVICES

The Company 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 TM System is placed into service. The annual agreements with the Company's customers to license the use of radiation and transfer devices are classified by the Company as operating leases. Income is recognized ratably over the length of the lease. At September 30, 2002, deferred revenue under these leases approximated $0.8 million.

During 2001, the Company estimated the useful lives of these assets to be 18 months based upon the information available at that time. During January 2002, the Company determined that, based upon new testing and experience, the estimated useful lives of RSTs are twelve months and the TDs are three years. Accordingly, depreciation has been recorded over the new estimated lives starting at the beginning of the first quarter 2002. The Company begins depreciation when the Beta-CathTM System is placed into service. At September 30, 2002, equipment with a cost of approximately $27.4 million, less $5.1 million reserve for impairment (See Note 11) before accumulated depreciation of approximately $10.7 million, was subject to operating leases. Approximately $3.3 million of radiation and transfer devices were available for lease at September 30, 2002. Radiation and transfer devices stated at cost, less impairment charge, are comprised of the following:

	September 30, 2002	December 31, 2001
Radiation and Transfer Devices	$ 22,393,212	$ 18,753,747
Less: Accumulated Depreciation	(10,686,329)	(5,219,391)
	$ 11,706,883	13,534,356

NOTE 6. RECEIVABLE FROM OFFICERS

In October 2001, the Company adopted a split-dollar life insurance plan for all officers. The Company matches officer contributions to the plan and also provides an advance for related payroll taxes. The payroll tax advance is reflected as a receivable from officers on the balance sheet. The advances are unsecured and are subject to the life insurance company's ability to repay the

Company in the future from the available funds. There were no related compensation expenses or payroll advances for the three-month period ended September 30, 2002. In accordance with the plan agreement, if an officer leaves the Company for any reason, retires or in any way terminates or withdraws from the plan, the life insurance company is obligated to repay the Company for the tax advances prior to settlement of the account with the officer. At September 30, 2002, and December 31, 2001, the receivable from officers balance was $279,829 and $144,025, respectively. One officer left the Company, reducing the receivable by $34,668 during the quarter.

The Company is re-evaluating the split dollar insurance program. The Sarbanes-Oxley Act of 2002 ("the Act") passed by Congress and signed into law in July 2002, may limit or effectively prevent implementation of programs like the Company's split dollar plan and we are currently evaluating the effect the Act has on this program. The Company has ceased accepting further contributions to the plan from Executive Officers until the analysis is concluded.

NOTE 7. LINE OF CREDIT

In August 2001, the Company obtained a $10 million revolving line of credit. During the nine months ended September 30, 2002 the Company had borrowed as much as $4 million against the line of credit; however, at September 30, 2002 and December 31, 2001, the Company had no outstanding borrowings. The Company may borrow an amount not to exceed the borrowing base as defined in the loan agreement which is principally based on domestic accounts receivables. Interest on outstanding balances is payable on the first of each month, calculated on the outstanding balance, and accrues at a rate of the bank's prime rate plus 1%. The Company granted a first priority security interest in substantially all assets of the Company to the lender. The Company was not in violation of any of its loan covenants at September 30, 2002. By agreement between the Company and the lender, dated August 31, 2002, the maturity date of the original Loan Agreement between the parties was extended to November 30, 2002. It is anticipated that a new revolving line of credit agreement, under similar terms, will be completed and executed prior to the expiration of the extended maturity date.

The Company also has letters of credit available under the revolving line of credit. The lender will issue or has issued letters of credit for the Company's account subject to certain limitations; however, all such issued letters of credit may not exceed $500,000 in the aggregate.

NOTE 8. SEGMENT INFORMATION

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

The Company's net sales, net loss and long-lived assets by geographic area at and for the nine months ended September 30 for 2002 and 2001 are as follows:

Net sales

	United States	Europe	Rest of World	Consolidated
2002	$50,833,347	$3,154,185	$424,569	$54,412,101
2001	$43,466,425	$3,527,056	$504,493	$47,497,974

Net loss

	United States	Europe	Rest of World	Consolidated
2002	$(5,668,243)	$(2,136,145)	$(631,499)	$(8,435,877)
2001	$(2,529,493)	$(4,844,912)	$(464,529)	$(7,838,934)

Long-lived assets

	United States	Europe	Rest of World	Consolidated
2002	$19,389,246	$2,363,735	$144,519	$21,897,500
2001	$20,039,478	$3,268,178	$113,411	$23,421,067

At September 30, 2002 and September 30, 2001, the Company's net assets outside of the United States, consisting principally of cash and cash equivalents, accounts receivable, transfer radiation devices and office equipment, were approximately $4.9 million and $6.5 million, respectively.

NOTE 9. EARNINGS (LOSS) PER SHARE

The basic and diluted income or loss per share is computed based on the weighted average number of common shares outstanding. Common equivalent shares are not included in the per share calculations where the effect of their inclusion would be anti-dilutive.

The following table sets forth the computation of basic and diluted earnings (loss) per share for the three and nine month periods ended September 30, 2002 and 2001:

	Three Months Ended September 30,		Nine Sep
	2002	2001	2002
Numerator:			
Net income (loss)	$(3,286,874)	$2,086,241	$(8,435,8
Denominator:			
Weighted-average shares outstanding	16,286,445	16,188,275	16,292,
Dilutive effect of stock options and unvested restricted stock	-	230,116	
Denominator for diluted earnings per share	16,286,445	16,418,391	16,292,
Net income (loss) per share:			
Basic	$(0.20)	$0.13	$(0.
Diluted	$(0.20)	$0.13	$(0.

NOTE 10. SHAREHOLDERS' EQUITY

For the three and nine month periods ended September 30, 2002 changes in shareholders' equity consisted of the following:

	Three Months	Nine
Shareholders' equity at beginning of period	$ 61,013,795	$
Proceeds from exercise of 56,375 stock options ranging from $1.00 to $6.65 per share	-	
Proceeds from issuance of stock under employee stock purchase plan, 24,497shares on 6/28/02 at $4.08 per share	-	
Stock re-purchase of 159,800 shares	(616,030)	
Deferred compensation relating to accelerated vesting of certain stock options	-	
Amortization of unearned compensation	42,587	
Cancellation of unvested compensation charge options	-	
Unrealized loss on held-for-sale securities	(6,000)	
Comprehensive loss:		
Translation adjustment	(213,602)	
Net income (loss)	(3,286,874)	
Total comprehensive loss	(3,500,476)	
Shareholders' equity at September 30, 2002	$ 56,933,876	$

NOTE 11. IMPAIRMENT CHARGES

The company accounts for long-lived assets in accordance with the provisions 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-CathTM System equipped with a 3.5F diameter catheter. Original plans were to introduce the product slowly; however, the smaller diameter system allows physicians to provide better and more comprehensive treatment to their patients, and demand for the new product exceeded expectations, with the first-year goal of installed sites being achieved in less than four months. While the older, larger 5.0F diameter Beth CathTM Systems are still serviceable, during the

second quarter of 2002, Novoste decided to concentrate marketing and development efforts on the 3.5F diameter Beta-CathTM System. Accordingly, the Company evaluated the ongoing value of the 5.0F systems that are equipped to use with 30mm and 40mm radiation source trains. Based on this evaluation, the Company determined that the transfer devices and radiation source trains, which are long-lived assets, with a carrying amount of $8.6 million, were no longer recoverable and wrote them down to their estimated fair value of $3.5 million, and accrued $1.8 million for related expenses, resulting in an impairment charge of $6.9 million for the second quarter. 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 (Note 1). As a result, demand for the 5.0F diameter system increased significantly to service the patients needing vascular brachytherapy. This increased demand should provide cash flow in excess of the carrying value. Thus no additional impairment charge was recorded in this quarter ended September 30, 2002.

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

FORWARD LOOKING INFORMATION

The statements contained in this Form 10-Q that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements regarding expectations, beliefs, intentions or strategies regarding the future. The Company intends that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect the Company's views as of the date they are made with respect to future events and financial performance, but are subject to many uncertainties and risks which could cause the actual results of the Company to differ materially from any future results expressed or implied by such forward-looking statements. Some of these risks are discussed below in the sections "Liquidity and Capital Resources" and "Certain Factors That May Impact Future Operations and Liquidity." Additional risk factors are discussed in other reports filed by the Company from time to time on Forms 10-K, 10-Q and 8-K, including the Company's annual report on Form 10-K for the year ended December 31, 2001. The Company does not undertake any obligations to update or revise any forward-looking statements, made by it or on its behalf, whether as a result of new information, future events, or otherwise.

CRITICAL ACCOUNTING POLICIES

The Company'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. Note 1 to the Consolidated Financial Statements discusses our significant accounting policies.

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. The Company 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(TM) System.

Novoste uses distributors in countries where the distributors' experience and knowledge of local radiation and medical device regulatory issues is considered beneficial by the Company'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(TM) System and completed all licensing and other requirements to use the system. The Company recognizes revenue from sales of catheters to distributors at the time of shipment.

The Company 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. No other post-sale obligations exist.

The Company sells its catheters with no right of return except in cases of product malfunction or shipping errors. A reserve has been recorded against revenue for known returns and an estimate of unknown returns. In connection with the introduction of the 3.5F catheter system in the second quarter of 2002 the Company exchanged some 5F catheters for 3.5F catheters for its customers. The exchange of these catheters was expected to continue in the future until the 3.5F system had been fully launched to all customer sites. At June 30, 2002, the Company had recorded a reserve for approximately $1,000,000 to recognize the 5F catheters purchased prior to June 30, 2002 that were expected to be returned in the future in exchange for 3.5F catheters. At September 30, 2002, a reserve of $750,000 is recorded to reflect management's estimate of 5.0F catheters sold prior to September 30, 2002 that are expected to be returned for 3.5F catheters upon FDA approval and re-launch of the 3.5F product.

Radiation and Transfer Devices and Amortization of Costs

The Company retains ownership of the radiation source trains (RSTs) and transfer

devices (TDs) that are manufactured by third party vendors. The costs to acquire, test and assemble these assets are recorded as incurred. The Company has determined that based upon experience, testing and discussions with the FDA the estimated useful life of RSTs and TDs exceeds one year and is potentially as long as four years. Accordingly, the Company 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- CathTM 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.

The Company has invested significant resources to acquire RSTs and TDs that make up the Beta-CathTM 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 the Company'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 3.5 F diameter Beta-CathTM System. Accordingly, the Company evaluated the recoverability of the carrying value for 5.0F devices and other assets to determine if an impairment charge was necessary. The Company 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 ("FAS 144"). Based on this evaluation, the Company determined that an impairment charge was warranted (See Note 11).

Stock Based Compensation

Novoste applies the provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ("FAS 123"). As permitted by FAS 123, the Company accounts for stock option grants in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25") and related interpretations. Accordingly, no compensation expense is recognized for stock option grants to employees for which the terms are fixed. The Company 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.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 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

We maintain 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.

Inventories

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

OVERVIEW

Novoste commenced operations as a medical device company in May, 1992. Beginning in 1994, the Company devoted substantially all of its efforts to developing the Beta-CathTM System. The Company commenced the active marketing of the Beta-CathTM System in Europe in January, 1999, for use as an adjunctive procedure in patients with ischemic heart disease. On November 3, 2000, Novoste received U.S. marketing approval for the 30-millimeter Beta-CathTM System from the FDA for use in patients suffering from in-stent restenosis, a condition in which coronary stents become clogged with new tissue growth, and shipped its first commercial system on November 27, 2000. The number of commercial sites in the U.S. increased rapidly throughout 2001, and in the first nine months of 2002, the Company added approximately 50 new sites, bringing the total U.S. sites to over 400 at September 30. The Company now has in excess of 500 commercial sites worldwide.

The Company is reporting an operating loss in the third quarter 2002 driven by lower revenues and the expense of recalling the 3.5F catheters as well as increased competition for vascular brachytherapy. At September 30, 2002 we had an accumulated deficit of approximately $129.8 million.

RESULTS OF OPERATIONS

Net loss for the three months ended September 30, 2002 was $3,286,874 or $(0.20) per share, as compared to a net income of $2,086,241 or $0.13 per share for the three months ended September 30, 2001. Net loss for the nine months ended September 30, 2002 was $8,435,877, or $(0.52) per share as compared to a net loss of $7,838,934, or $(0.49) per share for the nine months ended September 30, 2001. The net loss for the three months ended September 30, 2002 compared to the prior year was due primarily to the voluntary recall of the 3.5F catheter in the quarter.

The impact of the 3.5F catheter recall has been included in the consolidated financial statements of the Company and is recorded in the corresponding revenue and expense categories as appropriate based upon the nature of the expense or adjustment. Net sales were adjusted by approximately $3.0 million for 3.5F catheters that were sold to customers but subsequently returned due to the recall. Cost of sales reflects approximately $800,000 for the disposal of existing 3.5F catheters in inventory and for the additional labor and costs in shipping 5.0F transfer devices, radiation source trains and catheters to our customers. Operating expenses reflect the labor and material costs involved in

testing the 3.5F catheters in order to determine the proper corrective actions to be included in our reports to the FDA.

Net Sales. Net sales were $14,655,449 and $54,412,101 in the three and nine months ended September 30, 2002, respectively, as compared to net sales of $20,916,639 and $47,497,974 for the three and nine months ended September 30, 2001, respectively. Net sales recorded in the United States for the three and nine-month periods ended September 30, 2002 were $14,007,782 and $50,833,347 respectively, as compared to $19,437,626 and $43,466,425, respectively, for the same periods ended September 30, 2001. Comparatively, international net sales decreased 56% to $647,668 for the three-month period and 11% to $3,578,754 for the nine-month period in 2002, compared to $1,479,013 for the three-month period and $4,031,549 for the nine-month periods ending September 30, 2001.

Net sales declined for the quarter ended September 30, 2002 due primarily to the recall of the 3.5F catheter. Approximately $3.0 million of 3.5F catheters sold prior to the date of the recall were credited to customers' accounts. Catheter revenue was negatively impacted by the reserve for future 5.0F catheter exchanges, and lease revenue has declined because the higher lease revenue from the larger number of new sites opened in the first nine months of 2001 has not been replaced by lease revenue from the renewal of those sites. Although the sites continue to use the Beta-CathTM System, competitive pressure has not allowed the Company to charge continued leasing fees.

Revenues increased for the nine month period ended September 30, 2002 over the same period a year ago due entirely to the increase in the number of domestic sites utilizing the Beta-CathTM System at September 30, 2002 as compared to the same period in 2001.

The Company anticipates revenues to be at risk until, and if, the FDA approves the relaunch of the 3.5F catheter. The Company's primary competitor, Guidant, distributes a catheter size that is smaller than the 5.0F catheter that the Company is now dependent upon for its revenue. The smaller catheter can be a competitive advantage for Guidant. If other competitive advantages enjoyed by the Company are compromised by delays in, or failure to, obtain FDA approval to relaunch the 3.5F catheter. The Company's revenue may also be negatively impacted in 2003 and future years by the introduction of drug eluting stents.

Cost of Sales. Cost of sales of $6,774,235 and $26,566,655 were incurred in the three and nine months ended September 30, 2002, respectively. The nine-month period includes an impairment charge of $6.9 million (See Note 11), which negatively impacted gross margins. Reflecting cost of sales and impairment charges, gross margins for the three and nine month periods ending September 30, 2002 were $7,881214, or 56% and $27,845,445, or 51%, respectively. Excluding the impairment charge, gross margins were $7,881,214, or 56%, for the three months and $34,745,445 or, 64%, for the nine months. Cost of sales for the three and nine months ended September 30, 2001 were $5,118,949 and $14,589,293, respectively, and gross margins were 76%, or, $15,797,690, and $32,908,681 or, 69%, for the same periods respectively in 2001. The decrease in the gross margin for the third quarter of 2002 is due to higher amortization costs of the 5.0F devices as well as increased cost of sales due to the recall. The average selling price of the Company's catheters has also declined by approximately 5% for the nine months ending September 30, 2002 due to increased competition for vascular brachytherapy cases. The Company will continue to incur higher cost of sales until the 5.0F devices are fully amortized and the Company has re-launched its 3.5F catheter.

Factors impacting cost of sales and gross margins in future quarters will include the utilization of catheters at the sites using the Beta-CathTM System and the costs to service the existing devices as well as new 3.5F devices planned to be installed once the FDA has approved re-launching the 3.5F catheter.

Research and Development Expenses. Research and development expenses increased 19% to $3,501,473 and decreased 6% to $9,624,645 for the three and nine months ended September 30, 2002, respectively, from $2,941,372 and $10,261,939 for the three and six months ended September 30, 2001. The decrease for the nine month period was primarily the result of decreased clinical trial activity as a result of the completion of pivotal trials for the Beta-CathTM System used in coronary applications in 2001. However, in 2002, the Company began two new clinical trials to test the safety and effectiveness of radiation in peripheral applications which resulted in the increase in research and development expenditures for the three months ended September 30, 2002. The two trials, MOBILE (More Beta radiation In the Lower Extremities) and BRAVO (Beta Radiation for treatment of Arterial-Venous graft Outflow), have begun and the Company is currently enrolling clinical trial sites and patients. The Company anticipates increasing research and development expenses in the remainder of 2002 as it anticipates increased enrollment in the two new trials and as it pursues product improvements and line extensions in its current product offerings, some of which may require additional clinical trials.

Sales and Marketing Expenses. Sales and marketing expenses decreased 35% to $5,850,804 for the three months and 19% to $20,613,762 for nine months ended September 30, 2002, respectively, from $8,990,636 and $25,425,965 for the three and nine months ended June 30, 2001. These expenses declined because of lower product launch costs incurred in 2002 than in 2001. Additional costs such as commissions, travel, literature, trade shows, and samples were incurred last year to facilitate introduction of the Beta-CathTM System in the US market and the start-up procedures and training of new sites in 2001. The Company expects these costs to remain relatively constant as a percent of revenue for the balance of 2002.

General and Administrative Expenses. General and administrative expenses decreased 15% to $1,909,597 for the three months ended September 30, 2002 and increased 3% to $6,508,289 for the nine months ended September 30, 2002, from $2,252,761 and $6,739,757 for the three and nine months ended September 30, 2001. The decrease for the third quarter 2002 is mainly due to decreased costs associated with European operations and the consolidations of offices in Europe.

Other Income and Expenses. Other income decreased 80% to $93,786 for the three months ended September 30, 2002 and 69% to $515,376 for the nine months ended September 30, 2002, from $473,320 and $1,680,046 for the three and nine months ended September 30, 2001. The decrease is mainly due to the dramatic decline in interest rates for short-term investments. Interest income is down 110% from the same quarter last year and down 65% year to date. In addition, the Company incurred some interest costs associated with temporary borrowing from the line of credit.

LIQUIDITY AND CAPITAL RESOURCES

Operating

During the nine months ended September 30, 2002, the Company generated cash from operations of $6.1 million and for the nine months ended September 30, 2001 used $9.0 million of cash in operations. The $15.1 million change from cash used by operations to cash generated by operating activities was primarily attributable to decreasing accounts receivable in 2002 resulting from decreasing revenue, as opposed to the increase in accounts receivable in 2001 due to the product launch in the US. Other changes in inventory, accounts payable, accrued expenses and unearned revenue offset one another and between the periods reflect the increase in working capital needed in 2001 to fund the Beta-CathTM System launch offset by the decrease in working capital in the nine months ended September 30, 2002 as the number of sites, and revenue growth slowed.

Investing

Net cash provided by and used in investing activities for the nine months ended September 30, 2002 and 2001 was $6.0 million and $4.5 million, respectively. The construction of the plant for manufacturing 3.5F radiation source trains is complete. The decreased purchase of radiation devices in 2002 reflects the slower rate of opening new sites in 2002, maturity of the market place, with fewer transfer devices needed. The Company anticipates that the purchase of radiation devices will continue, although at a slower rate, as the Company converts accounts to the 3.5F System after it is re-launched.

Financing

The Company's financing activities include equity offerings, borrowings under a revolving credit facility and borrowings and repayments of capital leases. Proceeds from the issuance of stock were received from the exercise of stock options and the acquisition of stock by the Employee Stock Purchase Plan. The Company purchased 159,800 shares of its common stock at an average price of $3.855 under an authorized share repurchase program. The Company may decide, based upon market conditions and price of its common stock, to purchase additional shares. The total authorized repurchase was for up to $5 million, of which the remaining authorized repurchase is $4,384,00. Financing activities for the nine months ended September 30, 2002 and 2001 provided net cash of $0.3 million and $1.3 million, respectively, mainly through issuance of stock.

In August 2001, the Company entered into a $10 million accounts receivable revolving line of credit with a financial institution (lender) that matured in August 2002. By agreement between the Company and the financial institution, the maturity date of the original Loan Agreement between the parties was extended to November 30, 2002. At September 30, 2002, the Company had no outstanding borrowings. The Company may borrow an amount ("advances") not to exceed the borrowing base as defined in the loan agreement, which was $8.2 million at September 30, 2002. Interest is payable on the first of each month calculated on the outstanding balance and accrues at the rate of the lender's prime rate plus 1% (5.75% at September 30, 2002). At such time that the Company achieves three consecutive months of profitability, the rate decreases to the prime rate. The Company granted a first priority security interest in substantially all of its assets to secure the line of credit. Additionally, the loan agreement contains certain financial and non-financial covenants. The Company was not in violation of any of its loan covenants at September 30, 2002. It is anticipated that a new revolving line of credit agreement with the existing lender, under similar terms, will be completed and executed during the fourth quarter 2002.

In addition, the Company also has letters of credit available under the line of credit. The lender will issue or have issued letters of credit for the Company's account not exceeding (i) the lesser of the committed revolving line or the

borrowing base minus (ii) the outstanding principal balance of the Advances and

minus (iii) the Cash Management Sublimit as defined below; however, the aggregate face amount of all outstanding letters of credit (including drawn, but unreimbursed letters of credit) may not exceed $500,000. Each letter of credit will have an expiration date of no later than 180 days after the revolving maturity date, but the Company's reimbursement obligation will be secured by cash, on terms acceptable to the lender, at any time after the revolving maturity date, if the term of the Agreement is not extended by the Lender. The Company did not have any letters of credit outstanding at September 30, 2002.

The Company may use up to $500,000 for the Lender's Cash Management Sublimit, which may include merchant service, direct deposit of payroll, business credit card, and check cashing services identified in various cash management services agreements related to such services. All amounts the Lender advances under any such cash management services will be treated as advances under the committed revolving line.

Commitments

At September 30, 2002 the Company had commitments to purchase $2.1 million of inventory components for the Beta-Cath(TM) System over the next six months.

On June 20, 2001, the Company amended its manufacturing and supply agreement (Agreement) with Bebig Isotopen-und Medizintechnik GmbH, a German corporation (Bebig), to manufacture and supply the Company with radioactive sealed Strontium-90 seed trains. During each calendar year under the four-year contract, the Company guarantees to pay to Bebig minimum annual payments which will total $7.5 million over the tenure of the agreement. All product purchases are credited against the annual guaranteed payment. Any product payments in excess of the annual guaranteed payment can be credited against the guaranteed payment of the next year. In the event that the Company 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 year during the four-year contract period. The Company expects to exceed the guaranteed amount in 2002.

On October 14, 1999 the Company signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH for the development of a smaller diameter source. This agreement provided for the construction of a production line with a cost of construction estimated at $4.0 million and was paid by the Company as construction was completed. The final cost of construction was approximately $4.8 million and it became operational during the third quarter 2002.

Significant proportions of key components and processes relating to the Company'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, the Company's ability to produce the related product in a timely manner could be adversely affected. The Company attempts to mitigate these risks by working closely with key suppliers regarding the Company's product needs and the maintenance of strategic inventory levels.

The Company 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-CathTM System (excluding consideration paid for the radioactive isotope), subject to a maximum aggregate payment of $5,000,000. Royalty fees to the physician aggregated $132,899 and $191,312 for the three months ended September 30, 2002 and 2001, respectively, and have been expensed in Cost of Sales. As of September 30, 2002, aggregate payments of $1,218,153 have been made under the license

agreement.

On January 30, 1996, the Company entered into a license agreement whereby Emory University assigned its claim to certain technology to the Company for royalties based on net sales (as defined in the agreement) of products derived from such technology, subject to certain minimum royalties. After the first commercial sale of royalty bearing products by Novoste, minimum royalties were due to Emory University in the following amounts: year 2 after the first commercial sale - $10,000; year 3 - $15,000; year 4 - $25,000; and years 5-10 $50,000 per year. The royalty agreement term is consistent with the life of the related patent and applies to assignments of the patent technology to a third party. Royalty fees to Emory University aggregated $268,566 and $424,778 for the three months ended September 30, 2002 and 2001, respectively, and have been expensed in Cost of Sales.

Liquidity

The Company's principal source of liquidity at September 30, 2002 consisted of cash, cash equivalents and short-term investments of $33.4 million.

The Company had significant operating losses through the second quarter of 2001, but was profitable for the remaining two quarters of 2001 and in the first quarter of 2002. Although the third quarter shows a net loss, cash was generated by operations and the Company believes that existing cash and cash expected to be generated from operations will be sufficient to meet its working capital, financing and capital expenditure requirements for the foreseeable future. The Company's future liquidity and capital requirements will depend upon numerous factors, including the risks discussed at "Certain Factors That May Impact Future Operations And Liquidity" below, and the following, among others: market demand for its products; approval by the FDA to relaunch the 3.5F catheter; 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 TM System product line; the resources the Company devotes to the development, manufacture and marketing of its products; resources expended to license or acquire new technologies; and the progress of the Company'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.

We expect during the remainder of 2002 and first quarter of 2003 to allocate resources to prepare for and execute the relaunch of the 3.5F catheter when and if the FDA approves our pre-market approval supplement. Upon relaunch of the 3.5F catheter we will work to open additional 3.5F sites which will require additional purchases of transfer devices and radiation source trains. We believe 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.

RISK FACTORS

Voluntary Recall of Beta-Rail(TM) 3.5F Delivery Catheter

On August 19, 2002, the Company initiated a voluntary recall of the Beta-Rail(TM) 3.5F Delivery Catheter inventory from its customers. The recall

related to the discovery by the company of a small number of catheter-tip separations in the 3.5F 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, defining the improvements to the product and manufacturing processes and requesting approval for re-launch of the product. The FDA has one hundred and eighty (180) days to act on the PMA supplement with an approval or a denial to re-launch the product. Additionally, the FDA may require additional information from the company prior to acting on the application. A significant delay beyond the end of 2002 could impact the Company's competitive advantages in radiation licenses and negatively impact its market share. Failure to receive or delays in receipt of FDA approval to re-launch the product in a timely manner could have a material adverse effect on our business, financial condition and results of operations. Should the FDA deny the Company's request to relaunch the 3.5F catheter the Company would not be able to recover its investment in 3.5F technology and could substantially impair its ability to compete in vascular brachytherapy.

We Are Dependent On The Successful Commercialization Of One Product, The Beta-Cath(TM)System.

We began to commercialize the Beta-Cath TM System in the United States in November 2000. Substantially all of our revenue in the first nine months of 2002 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 TM System; however; in the future we may be unable to manufacture the Beta-Cath (TM) System in commercial quantities at acceptable costs or to demonstrate that the Beta-Cath (TM) 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 (TM) 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 TM 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 TM 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 TM 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. The Company may not be able to compete effectively against Johnson & Johnson or Guidant in the vascular brachytherapy market.

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 recently received unanimous recommendation for approval by a FDA advisory panel that its drug eluting stent be approved for distribution in the U.S. Full FDA approval could be expected as early as December 2002. If drug-eluting stents are approved for sale it could 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 CathTM System. We also have several additional United States applications pending covering other aspects of our Beta-CathTM 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 Will Be Expensive And Difficult.

Our Beta-CathTM System is regulated in the United States 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-CathTM System or new indications for the Beta-Cath System. 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, strict operator training requirements or other requirements as a condition of our market approval, any of which could limit our ability to market our systems. Labeling and marketing activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. FDA enforcement policy strictly prohibits the marketing of FDA cleared or approved medical devices for unapproved uses. Further, if a company wishes to modify a product after FDA approval of a pre-market approval, including any changes that could affect safety or effectiveness, additional approvals will be required by the FDA. Such changes include, but are not limited to: new indications for use, the use of a different facility to manufacture, changes to process or package the device, changes in vendors to supply components, changes in manufacturing methods, changes in design specifications and certain labeling changes. Failure to receive or delays in receipt of FDA approvals, including the need for additional clinical trials or data as a prerequisite to approval, or any FDA conditions that limit our ability to market our systems, could have a material adverse effect on our business, financial condition and results of operations.

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

Our business involves the import, export, manufacture, distribution, use and storage of Strontium-90 (Strontium/Yttrium), the beta-emitting radioisotope utilized in the Beta-CathTM System 's radiation source train. Hospitals in the United States are required to have radiation licenses to hold, handle and use radiation. Many of the hospitals and/or physicians in the United States have been required to amend their radiation licenses to include Strontium-90 prior to receiving and using our Beta-CathTM System. Depending on the state in which the hospital is located, its license amendment will be processed by and its use of the isotope will be regulated by The State of Georgia Department of Natural Resources ("DNR"), in agreement states, or by The United States Nuclear Regulatory Commission ("NRC"). Obtaining any of the foregoing radiation-related

approvals and licenses can be complicated and time consuming and may take longer in the NRC States (sixteen states). A significant majority of the approved license amendments have been in Non-NRC states. If a significant number of hospitals are delayed in obtaining approvals for the use of strontium-90, or if those approvals are not obtained or are withdrawn as a result of regulatory actions or sanctions, our business, financial condition and results of operation could be materially adversely affected.

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

In order for us to market the Beta-CathTM 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.

Item 3. Quantitative And Qualitative Disclosures About Market Risk

Interest Rate Risk

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

At September 30, 2002, the Company had $18.1 million in cash equivalents with a weighted average interest rate of 1.281% and $15.3 million in available-for-sale investments with a weighted average interest rate of 2.559%.

Item 4. Controls and Procedures

We maintain systems of internal controls and procedures for financial reporting ("Internal Controls") and disclosure controls and procedures ("Disclosure Controls") designed to provide reasonable assurance as to the reliability of our financial and other disclosures included in this report. Within the 90 days prior to the filing date of this quarterly report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), of the effectiveness of the design and operation of our Internal Controls and Disclosure Controls ("Controls Evaluation").

In the course of the Controls Evaluation, we sought to identify errors, controls problems and/or acts of fraud, and to confirm that appropriate corrective actions, including process improvements, were being undertaken. Among other matters, we sought to determine whether there were any "significant deficiencies" or "material weaknesses" in the Company's Internal Controls. In professional auditing literature, "significant deficiencies" are referred to as "reportable conditions"; they are control issues that could have a material

adverse effect on the ability to record, process, summarize and report financial data in the financial statements. A "material weakness" is defined in the auditing literature as a particularly serious reportable condition where the internal control does not reduce to a relatively low level the risk that misstatements caused by error or fraud may occur in amounts that would be material in relation to the financial statements and not be detected within a timely period by employees in the normal course of performing their assigned functions.

Subsequent to the 2001 audit performed by our independent auditors, Ernst & Young LLP ("E & Y"), the auditors identified and reported to management and to the Company's audit committee deficiencies, which were designated "reportable conditions" but not "material weaknesses". Based upon this report we have taken actions to address and correct the reportable conditions and strengthen our Internal Controls.

Our CEO and CFO have concluded that, subject to the inherent limitations in all control systems, our Disclosure Controls are effective in timely alerting them to material information relating to the Company that is required to be included in our periodic Securities and Exchange Commission filings, and that our Internal Controls are effective to provide reasonable assurance that our financial statements are fairly presented in conformity with generally accepted accounting principles.

We will continue to evaluate the effectiveness of our Controls Procedures and of the corrective actions we have taken with regard to the deficiencies noted by E & Y on an ongoing basis, and we will take such further actions as are dictated by such continuing reviews.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None

Item 2. Changes in Securities and Use of Proceeds

On October 16, 2002, the Board of Directors of the Company adopted two amendments to its Second Amended and Restated By-laws (the "By-laws"). In general, the amendments set forth certain notice requirements for shareholders when calling a special meeting of the Company's shareholders or submitting shareholder proposals (either a shareholder nomination of directors or other business) at annual meetings of the Company's shareholders. In addition, the amendment to the By-laws relating to the calling of a special meeting also establishes certain timing requirements for the setting of the record and meeting dates.

Specifically, the amendments provide that, in addition to any other applicable requirements, for a shareholder to properly call a special meeting, the shareholder must deliver to the Secretary of the Company written notice and must include in such notice certain required information. Business transacted at the special meeting will be limited to the purposes stated in such notice. The Secretary will determine if the notice complies with the information requirements set forth in the By-laws. If the Secretary determines that the notice complies with the information requirements set forth in the By-laws, the

Secretary will notify the Board of Directors. The Board of Directors will then meet or take action by written consent within 10 days from receiving such notice from the Secretary in order to fix (1) a record date to determine the shareholders entitled to receive notice of and to vote at the special meeting and (2) a date and location for the special meeting of shareholders. The record date set by the Board of Directors may not precede or be more than 10 days after the date of the meeting or written consent of the Board of Directors that fixed such record date. The date of the special meeting selected by the Board of Directors may not be earlier than 45 days or later than 70 days after the record date.

The amendments also provide that, in addition to any other applicable requirements, for a shareholder proposal (either a shareholder nomination of directors or other business) to be properly brought before an annual meeting of shareholders, a shareholder must have delivered to the Secretary written notice not less than 90 days nor more than 120 days prior to the first anniversary of the date of the annual meeting for the prior year, except in certain circumstances. Such written notice must set forth certain required information including, if applicable, that information regarding each of the director nominees that would otherwise be required by the proxy rules promulgated by the Securities and Exchange Commission.

The foregoing description of the amendments to the By-laws does not purport to be complete and is qualified in its entirety by reference to the amendments which are attached as Exhibit 99.1 to the Company's 8-K filed on October 17, 2002, and incorporated herein by reference.

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

None.

Item 6. Exhibits and Reports on Form 8-K

(a)

EXHIBIT NUMBER	DESCRIPTION
3.1	Articles of Incorporation of Registrant, as amended. (1)
3.2	Form of 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 Novoste Corporation filed with the Department of State of the State of Florida on November 1, 1996. (2)
3.3(a)	Copy of Amended and Restated By-Laws of Registrant adopted December 20, 1996. (3)
3.4	First Amendment to Second Amended and Restated By-Laws dated

October 16, 2002 (4)

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(1) Filed as same numbered Exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-4988).
(2) Filed as same numbered Exhibit to the Registrant's Report on Form 8-A/A filed on August 3, 1999.
(3) Filed as Exhibit A to the Registrant's Proxy Statement for its 2001 Annual Meeting of Stockholders filed on April 30, 2001.
(4) Filed as Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed on October 17, 2002.

(b) Reports on Form 8-K.

On August 20, 2002, the Company filed a current report on Form 8-K to disclose its voluntary recall of its Beta-Cath(TM) 3.5F delivery catheters.

On October 17, 2002, the Company filed a current report on Form 8-K to report the appointment of a new Chief Executive Officer and an amendment to the Company's Second Amended and Restated Bylaws.

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/Alfred J. Novak	/s/ Edwin B. Cordell, Jr.
ALFRED J. NOVAK Chief Executive Officer (Principal Executive Officer)	EDWIN B. CORDELL, JR. Vice President - Finance and Chief Financial Officer (Principal Financial & Accounting Officer)

November 14, 2002
Date

CERTIFICATIONS

I, Alfred J. Novak, certify that:

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

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

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

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

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

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

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

5. The registrant's other executive officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:

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

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

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

Date: November 14, 2002

/s/ ALFRED J. NOVAK

ALFRED J. NOVAK
Chief Executive Officer

CERTIFICATIONS

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

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

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

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

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

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

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

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

5. The registrant's other executive and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:

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

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

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

Date: November 14, 2002

/s/ EDWIN B. CORDELL, JR.

EDWIN B. CORDELL, JR.
Chief Financial Officer

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