

Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

- Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
- For the quarterly period ended June 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 July 31, 2002 there were 16,346,173 shares of the Registrant's Common Stock outstanding.

Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

NOVOSTE CORPORATION

FORM 10-Q

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

Consolidated Balance Sheets as of June 30, 2002 (unaudited)  
and December 31, 2001

Consolidated Statements of Operations (unaudited) for the three and six  
months ended June 30, 2002 and 2001

Consolidated Statements of Cash Flows (unaudited) for the six  
months ended June 30, 2002 and 2001

Notes to Unaudited Consolidated Financial Statements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

PART II. OTHER INFORMATION

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

Item 5. Other Information

Item 6. Exhibits and Reports on Form 8-K

SIGNATURES

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

NOVOSTE CORPORATION  
CONSOLIDATED BALANCE SHEETS

	June 30, 2002	Decem
	----- (Unaudited)	-----
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,594,765	\$
Short-term investments	17,648,393	
Accounts receivable, net of allowance of \$1,119,545 and \$878,424 respectively	13,108,113	
Inventory, net	3,976,539	
Prepaid expenses and other current assets	1,242,751	
	-----	-----
Total current assets	52,570,561	
Property and equipment, net	9,806,116	
Radiation and transfer devices, net	10,363,064	
Receivable from officers	314,497	
Other assets	1,058,715	
	-----	-----
Total assets	\$ 74,112,953	\$
	=====	=====
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,594,789	\$
Accrued expenses	7,924,814	
Unearned revenue	2,258,189	
Revolving Line of Credit	-	
Capital lease obligations	138,514	
	-----	-----
Total current liabilities	12,916,306	
Long-term liabilities		
Capital lease obligations	182,852	
	-----	-----
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	
Additional paid-in capital	187,478,589	
Accumulated other comprehensive income (loss)	265,066	
Accumulated deficit	(126,532,530)	
	-----	-----
	61,374,645	
Less treasury stock, 5,780 shares of common stock at cost	(23,840)	
Unearned compensation	(337,010)	
	-----	-----
Total shareholders' equity	61,013,795	
Total liabilities and shareholders' equity	\$ 74,112,953	\$
	=====	=====

See accompanying notes.

1489942v3

NOVOSTE CORPORATION  
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		
	2002	2001	2000
Net sales	\$ 16,824,300	\$ 17,290,707	\$ 39,000,000
Cost of sales	6,214,300	5,725,840	12,000,000
Impairment charge	6,900,000	0	6,000,000
Gross margin	3,710,000	11,564,867	19,000,000
Operating expenses:			
Research and development	3,464,246	3,724,430	6,000,000
Sales and marketing	6,544,863	9,149,095	14,000,000
General administrative	2,293,249	2,576,295	4,000,000
Total operating expenses	12,302,358	15,449,820	25,000,000
Loss from operations	(8,592,358)	(3,884,953)	(5,000,000)
Interest income, interest expense and other, net	40,864	588,347	0
Loss before income taxes	(8,551,494)	(3,296,606)	(5,000,000)
Income taxes	0	0	0
Net loss	\$ (8,551,494)	\$ (3,296,606)	\$ (5,000,000)
Net loss per share - basic and diluted	\$ (0.52)	\$ (0.20)	\$ (0.50)
Weighted average shares outstanding basic and diluted	16,311,496	16,131,974	16,000,000

See accompanying notes.

NOVOSTE CORPORATION  
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

	For The Six Months June 30, 2002	
Cash flows from operating activities:		
Net income (loss)	\$ (5,149,002)	\$
Adjustments to reconcile net income (loss) to net cash used by operating activities:		
Depreciation and amortization	1,099,788	
Issuance (cancellation) of stock for service or compensation	196,875	
Amortization of deferred compensation	96,681	
Amortization of radiation & transfer devices	6,029,897	
Provision for doubtful accounts	241,121	
Changes in assets and liabilities:		
Accounts receivable	2,988,355	
Inventory	(260,106)	
Prepaid expenses	(219,705)	
Accounts payable	(1,303,762)	
Accrued expenses and taxes withheld	(4,824,768)	
Unearned revenue	(553,330)	
Impairment Charge	5,065,000	
Other	397,213	
Net cash generated (used) by operations	3,604,317	
Cash flow from investing activities:		
Maturity (purchase) of short-term investments	14,035,234	
Purchase of property and equipment, net	(999,822)	
Purchase of radiation and transfer devices	(6,073,605)	
Net cash (provided by and used by) investing activities	6,961,807	
Cash flows from financing activities:		
Proceeds from issuance of common stock	468,397	
Repayment of capital lease obligations	(130,981)	
Net cash provided by financing activities	337,416	
Effect of exchange rate changes on cash	(187,060)	
Net increase (decrease) in cash and cash equivalents	10,716,479	
Cash and equivalents at beginning of period	5,878,286	
Cash and cash equivalents at end of period	\$ 16,594,765	\$
SUPPLEMENTAL DISCLOSURE OF CASH FLOW		
Information:		
Cash paid for interest	\$ (20,718)	\$
Non-cash investing and financing activities:		
Assets acquired under capital lease	\$ 0	\$

See accompanying notes.

NOVOSTE CORPORATION  
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS  
June 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 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 2002. Significant intercompany transactions and accounts have been eliminated.

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 June 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 June 30, 2002 and December 31, 2001 includes 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

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

collateral. Management records estimates of expected credit losses and returns of product sold. Bad debt expense for the three-month periods ended June 30, 2002 and 2001 amounted to \$158,265 and \$200,000, respectively, and for the six-month periods were \$164,107 and \$300,000.

6

### NOTE 4. INVENTORIES

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

	June 30, 2002	December 31, 2001
	-----	-----
Raw Materials	\$ 2,852,217	\$ 1,971,347
Work in Process	419,677	811,406
Finished Goods	704,645	963,680
	-----	-----
Total	\$ 3,976,539	\$ 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 recorded in cost of sales. Depreciation begins once 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.

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 still begins depreciation when the Beta-Cath(TM) System is placed into service and accounts for annual agreements to license the Beta-Cath(TM) System as leases. Income is recognized ratably over the length of the lease. At June 30, 2002, deferred revenue under these leases approximated \$1.3 million. At June 30, 2002, equipment with a cost of approximately \$24.8 million less \$5.1 million reserve for impairment (See Note 11) before accumulated depreciation of approximately \$9.4 million, was subject to operating leases. Approximately \$3.2 million of radiation and transfer devices were available for lease at June 30, 2002. Radiation and transfer devices are stated at cost and less impairment charge are comprised of the following:

June 30, 2002

December 31, 2001

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

Radiation and Transfer Devices	\$ 19,777,352	\$ 18,753,747
Less: Accumulated Depreciation	(9,414,288)	(5,219,391)
	\$ 10,363,064	\$ 13,534,356
	\$ 10,363,064	\$ 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. During the three months ended June 30, 2002, the Company made matching contributions of approximately \$7,000 but made no related advances for payroll taxes. There were no similar compensation expenses or payroll advances for the three-month period ended June 30, 2001. Payroll advances provided to officers of the Company are reflected as receivables from officers on the balance sheet. 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, then the life insurance company is obligated to repay the Company for the tax advances prior to settlement of the account with the officer. The advances are unsecured and are subject to the life insurance company's ability to repay the Company in the

7

future from the available funds. At June 30, 2002 and December 31, 2001, the receivable from officers balance was \$314,497 and \$144,025, respectively.

### NOTE 7. LINE OF CREDIT

In August 2001, the Company obtained a \$10 million revolving line of credit. During the six months ended June 30, the Company had borrowed as much \$4 million; however, at June 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, 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 June 30, 2002. By agreement between the Company and the lender, dated July 30, 2002, the maturity date of the original Loan Agreement between the parties was extended to August 31, 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 have issued letters of credit for the Company's account subject to certain limitations; however, they 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



## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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 income or loss from operations and long-lived assets by geographic area at and for the six months ended June 30 for 2002 and 2001 are as follows:

Net sales	United States -----	Europe -----	Rest of World -----	Consolidated -----
2002	\$36,825,566	\$2,618,630	\$312,456	\$39,756,652
2001	24,028,800	2,124,193	428,343	26,581,336

8

Net Income (Loss)	United States -----	Europe -----	Rest of World -----	Consolidated -----
2002	\$ (3,333,985)	\$ (1,487,388)	\$ (327,629)	\$ (5,149,002)
2001	(7,009,801)	(2,841,898)	(73,475)	(9,925,174)

Long-lived assets	United States -----	Europe -----	Rest of World -----	Consolidated -----
2002	\$18,013,188	\$2,019,201	\$136,791	\$20,169,180
2001	16,453,494	798,188	105,096	17,356,778

At June 30, 2002 and December 31, 2001, the Company's net assets outside of the United States, consisting principally of cash and cash equivalents, accounts receivable, transfer devices and office equipment, were approximately \$5.4 million and \$4.8 million, respectively.

### NOTE 9. EARNINGS (LOSS) PER SHARE

The basic and diluted 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 antidilutive.

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

	Three Months Ended June 30,	
	2002	2001
Numerator:		

Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

Net income (loss)	\$ (8,551,494)	\$ (3,296,606)
Denominator:		
Weighted-average shares outstanding	16,311,496	16,131,974
Net income (loss) per share:		
Basic and diluted	\$ (0.52)	\$ (0.20)

9

NOTE 10. SHAREHOLDERS' EQUITY

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

	Three Months	
	-----	-----
Shareholders' Equity at beginning of period	\$ 68,833,803	\$
Proceeds from exercise of 5,000 and 56,375 stock options ranging from \$1.00 to \$6.65 per share	5,000	
Proceeds from issuance of stock under employee stock purchase plan, 25,497 shares on 6/28/02 at \$4.08 per share	104,028	
Deferred compensation relating to accelerated vesting of certain stock options		
Amortization of unearned compensation	45,743	
Comprehensive loss:		
Translation adjustment	576,715	
Net income (loss)	(8,551,494)	
	-----	-----
Total comprehensive loss	(7,974,779)	
Shareholders' Equity at June 30, 2002	\$ 61,013,795	\$
	=====	=====

NOTE 11. IMPAIRMENT CHARGES

In March 2002, Novoste began commercial distribution of a newer, smaller Beta-Cath (TM) System equipped with a 3.5F diameter catheter. Original plans were to introduce the product slowly; however, the smaller diameter system allows physicians to provide better and more comprehensive treatment to their patients, and demand for the new product exceeded expectations, with the first-year goal of installed sites being achieved in less than four months. While the older, larger 5.0F diameter Beth Cath systems are still serviceable, during Q2 of 2002, Novoste decided to concentrate marketing and development

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

efforts on the 3.5 F diameter Beta-Cath (TM) System and phase out the older 5.0F systems. Accordingly, the Company evaluated the ongoing value of these older systems that are equipped to use with 30mm and 40mm radiation source trains. Based on this evaluation, the Company determined that the radiation devices, 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 radiation devices during their remaining service lives, discounted at the risk-free rate of interest. Because of uncertain market conditions and the rate of exchange of the older systems for the newer systems, it is reasonably possible that our estimate of discounted cash flows may change in the near term resulting in the need to adjust our determination of fair value.

10

### 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

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

require the use of estimates and assumptions. Note 1 to the Consolidated Financial Statements discusses all 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 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 once 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

11

United States requires, as dictated by FDA regulatory approval, replacement and servicing of the radiation source train and transfer device at six-month intervals. No other post-sale obligations exist.

The Company sales 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 has exchanged some 5F catheters for 3.5F catheters for its customers. The exchange of these catheters is likely to continue in the future until the 3.5F system has been fully launched to all customer sites. For the three-month period ended June 30, 2002 the Company has recorded a reserve for approximately \$1,000,000 to recognize that some 5F catheters purchased prior to June 30, 2002 may be exchanged in the future for 3.5F catheters. Although these 5F catheters can be resold, the Company believes it is prudent to postpone the recognition of this revenue until the exchanges have been completed or the likelihood of exchange has subsided. The Company has recorded this amount based upon its estimates of 5F catheters at customers sites and the anticipated demand by its customers for exchanges. The amount of future exchanges could differ from the amount recorded at June 30, 2002.

### 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

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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 once the Beta-Cath(TM) System is placed into service. Valuation allowances are recorded for 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-Cath (TM) 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 made based upon available information from Sales and Marketing. 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-Cath (TM) System and phase out the older 5.0F systems. Accordingly, the Company evaluated the recoverability of the carrying value for 5F 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 options 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

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

recorded in the allowances is based primarily on management's evaluation of the financial condition of the customers. If the financial condition of our 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 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-Cath(TM) System. The Company commenced the active marketing of the Beta-Cath(TM) 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-Cath(TM) 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 six months of 2002, the Company added 36 new sites, bringing the total to 390 at June 30.

Since our inception through June 30, 2001 we experienced significant losses in each period due to product development and clinical trial costs and, beginning in 2000, the costs of launching the Beta-Cath(TM) System in the U.S. The Company recognized its first net operating profit in the third quarter of 2001. This quarterly profit resulted from positive acceptance of the Beta-Cath(TM) System launched earlier in the year, as revenue covered the extensive support infrastructure developed to support the customer base using the new product. The quarter also saw reduced expenses for research and development as clinical trials associated with the Beta Cath System decreased.

Profitability continued during the fourth quarter of 2001 and the first quarter of 2002 as growth in sites and product demand exceeded expectations. Gross margins were the highest of the year as catheter revenue increased significantly to cover the costs of placing the Beta-Cath(TM) System in service at customer sites. Also during the quarter, the Company initiated an effort to reduce costs in Europe to bring expenditures more in line with business volume.

The Company is reporting an operating loss in the second quarter 2002 driven by lower revenues and the expense of transitioning from the 5F Beta-Cath(TM) System to the 3.5F system. In addition, a reserve against revenue and an impairment charge against 5F assets was recorded during the second quarter. At June 30, 2002 we had an accumulated deficit of approximately \$126.6 million.

### RESULTS OF OPERATIONS

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

Net loss for the three months ended June 30, 2002 was \$8,349,488 or \$(0.51) per share, as compared to a net loss of \$3,296,606 or \$(0.20) per share for the three months ended June 30, 2001. Net loss for the six months ended June 30, 2002 was \$4,946,997, or \$(0.30) per share as compared to a net loss of \$9,925,174, or \$(0.62) per share for the six months ended June 30, 2001. The increase in net loss for the three months ended June 30, 2002 compared to the year earlier periods was primarily due to lower revenue and the expense of transitioning from the 5F Beta-Cath (TM) System to the 3.5F System and the impairment charge against the 5F assets. The lower loss in the six months ended June 30, 2002 was due to the issues impacting second quarter net loss, offset by higher revenues and lower costs compared to the year earlier periods due to an increase in revenue for sales in the US market from the commercial launch of the Beta-Cath (TM) System.

Net Sales. Net sales were \$16,824,300 and \$39,756,652 in the three and six months ended June 30, 2002, respectively, as compared to net sales of \$17,290,707 and \$26,581,336 for the three and six months ended June 30, 2001, respectively. Net sales recorded in the United States for the three and six month periods ended June 30, 2002 were \$15,378,734 and \$36,825,566 respectively, as compared to \$16,039,613 and \$24,028,800, respectively, for the same periods ended June 30, 2001. Comparatively, international net sales increased 16% to \$1,445,566 for the three-month period and 15% to \$2,931,086 for the six-month period in 2002, compared to \$1,251,094 for the 3- month period and \$2,552,536 for the six-month period in 2001. International sales increased from the prior year due to adding sites in other parts of the world.

Net sales declined for the quarter ended June 30, 2002 due to lower catheter revenue and lease revenue. Catheter revenue was negatively impacted by the reserve for future catheter exchanges, and lease revenue has declined because the higher lease revenue from the larger number of new sites opened in the first half of 2001 has not been replaced by lease revenue from the renewal of those sites. Although the sites continue to use the Beta-Cath (TM) System, competitive pressure has not allowed the Company to charge continued leasing fees. Excluding the reserve for future catheter exchanges recorded in the quarter, catheter revenue, as did unit volume, would have increased over the second quarter of 2001 based upon the larger number of sites now using the Beta-Cath (TM) System at June 30, 2002 than at June 30, 2001.

Revenues increased for the six month period ended June 30, 2002 over the same period a year ago due entirely to the approximately doubling of the number of domestic sites utilizing the Beta-Cath (TM) System at June 30, 2002 as compared to June 30, 2001. During the second quarter Novoste began commercial deployment of a new Beta-Cath (TM) System with smaller, 3.5F diameter catheters. This new system is expected to expand the market opportunity by allowing access to smaller arteries in the patient. In many, but not all, applications, the 3.5 F System can replace the older 5.0 F Beta-Cath (TM) System, thus, we expect to experience reduced revenue from the older units as market penetration of the new system proceeds. (See the discussion of the impairment charge in Note 12.)

Cost of Sales. Cost of sales of \$6,214,300 and \$12,892,421 were incurred in the three and six months ended June 30, 2002, respectively. In addition, an impairment charge of \$7.0 million in the three months ended June 30, 2002 (See Note 12), negatively impacted gross margins for the three and six month periods. Reflecting cost of sales and impairment charges, gross margins for the three and six month periods ending June 30, 2002 were \$3,610,000, or 21% and \$19,864,231, or 50%, respectively. Excluding the impairment charge, gross margins were \$10,610,000, or 63%, for the three months and \$26,864,231 or, 68%, for the six months. Cost of sales for the three and six months ended June 30, 2001 were \$5,725,840 and \$9,470,344, respectively, and gross margins were 67%, or, \$11,564,867, and \$17,110,992 or, 64%, for the same periods respectively in 2001. The decrease in the gross margin for the second quarter of 2002 is due to the

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

higher costs of maintaining more transfer devices and radiation source trains in the larger number of sites in 2002. The six-month gross margins on both an absolute and percentage basis increased due to the higher revenue volume. Cost of sales includes raw material, labor and overhead to manufacture catheters as well as the amortized costs of transfer devices and radiation source trains and the service costs on those transfer devices used in the Beta-Cath(TM) System. Factors impacting cost of sales and gross margins in future quarters will include the utilization of catheters at the sites using the Beta-Cath (TM) System and the costs to service the existing devices as well as the new 3.5F devices currently being launched.

14

**Research and Development Expenses.** Research and development expenses decreased 7% to \$3,464,246 and 16% to \$6,123,172 for the three and six months ended June 30, 2002, respectively, from \$3,724,430 and \$7,320,567 for the three and six months ended June 30, 2001, respectively. These decreases were primarily the result of decreased clinical trial activity related to the completion of pivotal trials for the Beta-Cath (TM) System used in coronary applications in 2001. The Company has however begun two new clinical trials to test the safety and effectiveness of radiation in peripheral applications. 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 pursues product improvements and line extensions, some of which may require additional clinical trials.

**Sales and Marketing Expenses.** Sales and marketing expenses decreased 28% to \$6,544,863 for the three months and 10% to \$14,762,959 for six months ended June 30, 2002, respectively, from \$9,149,095 and \$16,435,329 for the three and six months ended June 30, 2001, respectively. These expenses declined because of lower product launch costs incurred in 2002 than in 2001. Extra costs such as commissions, travel, literature, trade shows, and samples were incurred last year to facilitate introduction of the Beta-Cath (TM) 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 consistent as a percent of revenue for the balance of 2002.

**General and Administrative Expenses.** General and administrative expenses decreased 11% to \$2,293,249 for the three months ended June 30, 2002 and increased 0.1% to \$4,490,673 for the six months ended June 30, 2002, from \$2,576,296 and \$4,486,996 for the three and six months ended June 30, 2001, respectively. The decrease for the quarter is mainly due to decreased costs associated with European operations and the consolidations of offices in Europe.

**Total Other Income and Expenses.** Total other income decreased 85% to \$40,864 for the three months ended June 30, 2002 and 74% to \$313,571 for the six months ended June 30, 2002, from \$272,707 and \$1,206,726 for the three and six months ended June 30, 2001, respectively. The decrease is mainly due to the dramatic decline in interest rates for short-term investments. Interest income is down 75% from the same quarter last year and down 41% year to date. In addition the company incurred some interest costs associated with temporary borrowing from the line of credit.

### LIQUIDITY AND CAPITAL RESOURCES

During the six months ended June 30, 2002, the Company generated cash from



## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

operations of \$3.6 million and for the six months ended June 30, 2001 used \$14.4 million of cash in operations. The \$18.0 million change from cash used by operations to cash generated by operating activities was the result of an improvement in operating results of approximately \$4.8 million and a reserve expense of \$6.9 million for the asset impairment. The improvement in operating cash results was primarily attributable to decreasing accounts receivable in the second quarter of 2002 because of decreasing revenue as opposed to the increase in accounts receivable in the second quarter of 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-Cath (TM) System launch offset by the decrease in working capital in the six months ended June 30, 2002 as the number of sites, and revenue growth slowed.

Net cash provided by and used in investing activities for the six months ended June 30, 2002 and 2001 was \$7.0 million and \$5.7 million, respectively. The decline in capital equipment purchases over the prior year is due to a slower rate of opening new sites in 2002. The construction of the plant for 3.5F radiation source trains is complete. The increased purchase of radiation devices in 2002 reflects the larger number of sites that use the Beta-Cath (TM) System. The purchase of radiation devices will continue, although at a slower rate, as the Company continues to convert its accounts to the 3.5F System.

15

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. Financing activities for the six months ended June 30, 2002 and 2001 provided net cash of \$0.3 million and \$54.3 million, respectively. During the quarter, the company repaid borrowings under the revolving line of credit of \$4.0 million.

In August 2001, the Company entered into a \$10 million accounts receivable revolving line of credit with a financial institution (lender) that matures in August 2002. At June 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 June 30, 2002. Interest is payable on the first of each month calculated on the outstanding balance and accrues at a rate of the lender's prime rate plus 1% (5.75% at June 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 June 30, 2002. By agreement between the Company and the financial institution, dated July 30, 2002, the maturity date of the original Loan Agreement between the parties was extended to August 31, 2002. It is anticipated that a new revolving line of credit agreement with the existing lender, under similar terms, will be completed and executed prior to the expiration of the extended maturity date.

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 expiry date of no later than 180 days after the revolving maturity

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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 this Agreement is not extended by the Lender. The Company agrees to execute any further documentation in connection with the letters of credit as the lender may reasonably request. The Company did not have any letters of credit outstanding at June 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 pays for any such cash management services will be treated as advances under the committed revolving line. The company expects to renew the credit facility when it expires in August with the current lender.

At June 30, 2002 the Company had commitments to purchase \$4.9 million in inventory components of the Beta-Cath(TM) System over the next six months.

On June 20, 2001, the Company entered into a 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 totaling \$7.5 million. 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. For 2001, the Company exceeded the annual guaranteed payments and expects to do so in 2002.

On October 14, 1999 the Company signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH for a second source of radioisotope supply and for the development of a smaller diameter source. This agreement provides for the construction of a production line with a cost estimated at \$4.0 million and was paid by the Company as construction was completed. Through June 30, 2002, the Company has paid \$4.0 million towards this commitment. The plant is expected to become operational during the third quarter 2002.

16

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-Cath(TM) System (excluding consideration paid for the radioactive isotope), subject to a maximum aggregate payment of \$5,000,000. Royalty fees to the physician aggregated \$169,534 and \$154,042 for the three months ended June 30, 2002 and 2001, respectively, and have been expensed in Cost of Sales. As of June 30, 2002, aggregate payments of \$1,085,254 have been made under the license

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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 shall be due to Emory University in the following amounts: year 2 after the first commercial sale - \$10,000.00; year 3 - \$15,000.00; year 4 - \$25,00.00; and years 5-10 \$50,000.00 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 \$347,985 and \$367,664 for the three months ended June 30, 2002 and 2001, respectively, and have been expensed in Cost of Sales.

The Company's principal source of liquidity at June 30, 2002 consisted of cash, cash equivalents and short-term investments of \$34.2 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 second 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; 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 to continue to allocate resources to leverage our existing manufacturing operations, both internally and with outside vendors. We expect our sales and marketing efforts in support of United States market development to level off as a percent of net sales and anticipate that our administrative activities to support our growth will remain at a constant level. These factors should generate positive operating cash flow. At the same time we will continue to conduct clinical trials and research and development projects in order to expand the opportunities for our technology, which could require the use of existing cash reserves.

17

### CERTAIN FACTORS THAT MAY IMPACT FUTURE OPERATIONS AND LIQUIDITY

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 six months of 2002 was from sales in the United States. We anticipate that for the foreseeable future we will be solely dependent on the 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

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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.

Coated 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 approximately 75% 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 in the vascular brachytherapy market.

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.

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. Recently, results from early trials were reported as eliminating restenosis. If additional trials are successful and completed in the time frames contemplated by the companies developing coated stents, coated stents, if approved for sales, could have a material adverse effect on Novoste's business. At least one competitor, Johnson & Johnson, could receive FDA approval as early as 2003.

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(TM) System. We also have several additional United States applications pending covering other aspects of our Beta-Cath(TM) 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.

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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

18

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 recently 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-Cath(TM) 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-Cath(TM) 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, 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

## Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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-Cath(TM) System 's radiation source train. Hospitals in the

19

United States are required to have radiation licenses to hold, handle and use radiation. Many of the hospitals and/or physicians in the United States have been required to amend their radiation licenses to include Strontium-90 prior to receiving and using our Beta-Cath(TM) System. Depending on the state in which the hospital is located, its license amendment will be processed at and its use of the isotope will be regulated at 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 stroutium-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-Cath(TM) 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

Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

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 June 30, 2002, the Company had \$16.6 million in cash equivalents with a weighted average interest rate of 1.05% and \$17.6 million in available-for-sale investments with a weighted average interest rate of 3.07%.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None

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 Securityholders

20

(a) The Company held its annual meeting of stockholders on June 12, 2002 and solicited votes by proxy in connection with such meeting.

(b) The following matters were approved by the shareholders:

(i) The approval of management's nominees to the Board of Directors with the nominees receiving the following votes:

	FOR	AGAINST	WITHHELD
Norman R. Weldon	13,906,561	79,670	--
Thomas D. Weldon	13,906,561	79,670	--
Charles E. Larsen	13,906,561	79,670	--

(ii) The shareholders approved on amendment to the Company's 2001 Stock Plan to increase the number of Shares of Common Stock reserved under the Plan to a total with 9,102,776 votes in favor, 4,765,010 against and 118,445 abstained.

(iii) The ratification of the appointment of Ernst & Young LLP as independent auditors of the Company for the year ending December 31, 2002. The proposal received 13,904,273 votes in favor, 75,548 against and 6,410 abstained.

Item 5. Other Information

None.

Item 6. Exhibits and Reports on Form 8-K

(a)

EXHIBIT NUMBER	DESCRIPTION
99.1	Certification of Periodic Financial Reports

Edgar Filing: NOVOSTE CORP /FL/ - Form 10-Q

(b) Reports on Form 8-K.

No reports on Form 8-K were filed or required to be filed during the quarter ended June 30, 2002.

21

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

August 14, 2002

/s/ Edwin B. Cordell, Jr.

-----  
Date

-----  
Edwin B. Cordell, Jr.  
Vice President - Finance,  
Chief Financial Officer  
(Principal Financial & Accounting Officer)

22

1489942