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NOVOSTE CORP /FL/  
Form 10-Q  
May 15, 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 March 31, 2002

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Transition period pursuant to Section 13 or 15(d) of the Securities  
Exchange Act of 1934.

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

0-20727

-----  
(Commission File Number)

Novoste Corporation

-----  
(Exact Name of Registrant as Specified in Its Charter)

Florida  
-----  
(State or Other Jurisdiction of  
Incorporation or Organization)

59-2787476  
-----  
(I.R.S. Employer  
Identification No.)

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

30093  
-----  
(Zip Code)

Registrant's telephone, including area code: (770) 717-0904

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 May 1, 2002 there were 16,315,676 shares of the Registrant's Common Stock  
outstanding.

NOVOSTE CORPORATION

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FORM 10-Q

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NOVOSTE CORPORATION  
UNAUDITED CONSOLIDATED BALANCE SHEETS

|  | March 31,<br>2002<br>-----<br>(Unaudited) |
|--|---|
| Assets   |   |
| Current assets:  |   |
| Cash and cash equivalents  | \$ 17,544,697                             |
| Short-term investments   | 21,901,407                                |
| Accounts receivable, net of allowance of \$870,445 and \$878,424 |   |

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|   |               |
|---|---------------|
| respectively  | 17,030,521    |
| Inventories   | 4,300,488     |
| Prepaid expenses and other current assets   | 1,010,237     |
|   | -----         |
| Total current assets  | 61,787,350    |
|   | -----         |
| Property and equipment, net   | 9,741,165     |
| Radiation and transfer devices, net   | 13,265,692    |
| Receivable from officers  | 314,497       |
| Other assets  | 829,929       |
|   | -----         |
| Total assets  | \$ 85,938,633 |
|   | =====         |
| Liabilities and Shareholders' Equity  |               |
| Current liabilities:  |               |
| Accounts payable  | \$ 4,380,232  |
| Accrued expenses  | 6,501,707     |
| Deferred revenue  | 1,834,612     |
| Revolving Line of Credit  | 4,000,000     |
| Capital lease obligations   | 205,427       |
|   | -----         |
| Total current liabilities   | 16,921,978    |
|   | -----         |
| Long-term liabilities   |               |
| Capital lease obligations   | 182,852       |
|   | -----         |
| Shareholders' equity:   |               |
| Preferred stock, \$.01 par value, 5,000,000 shares authorized;<br>no shares issued and outstanding                    | -             |
| Common stock, \$.01 par value, 25,000,000 shares authorized;<br>16,321,456 and 16,265,081 shares issued, respectively | 163,215       |
| Additional paid-in-capital  | 187,912,722   |
| Accumulated other comprehensive income (loss)   | (311,649)     |
| Accumulated deficit   | (117,981,036) |
|   | -----         |
|   | 69,783,252    |
| Less treasury stock, 5,780 shares of common stock at cost   | (23,840)      |
| Unearned compensation   | (925,609)     |
|   | -----         |
| Total shareholders' equity  | 68,833,803    |
|   | -----         |
| Total liabilities and shareholders' equity  | \$ 85,938,633 |
|   | =====         |

See accompanying notes.

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NOVOSTE CORPORATION  
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

|               | Three months ended March 31, |              |
|---------------|------------------------------|--------------|
|               | 2002                         | 2001         |
|               | -----                        | -----        |
| Net sales     | \$ 22,932,352                | \$ 9,290,629 |
| Cost of sales | 6,678,121                    | 3,744,504    |
|               | -----                        | -----        |

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|   |              |                |
|---|--------------|----------------|
| Gross margin                                    | 16,254,231   | 5,546,125      |
|   | -----        | -----          |
| Operating expenses:                             |              |                |
| Research and development                        | 2,658,926    | 3,596,137      |
| Sales and marketing                             | 8,218,096    | 7,286,234      |
| General and administrative                      | 2,197,424    | 1,910,700      |
|   | -----        | -----          |
| Total operating expenses                        | 13,074,446   | 12,793,071     |
|   | -----        | -----          |
| Income (loss) from operations                   | 3,179,785    | (7,246,946)    |
|   | -----        | -----          |
| Interest income                                 | 370,878      | 642,918        |
| Interest expense                                | (98,171)     | (24,539)       |
|   | -----        | -----          |
| Total other income                              | 272,707      | 618,379        |
|   | -----        | -----          |
| Income (loss) from operations before income tax | 3,452,492    | (6,628,567)    |
| Income tax                                      | 50,000       | -              |
|   | -----        | -----          |
| Net income (loss)                               | \$ 3,402,492 | \$ (6,628,567) |
|   | =====        | =====          |
| Net income (loss) per share - basic             | \$ 0.21      | \$ (0.41)      |
|   | =====        | =====          |
| Weighted average shares outstanding - basic     | 16,280,182   | 16,076,974     |
|   | -----        | -----          |
| Net income (loss) per share - diluted           | \$ 0.21      | \$ (0.41)      |
|   | =====        | =====          |
| Weighted average shares outstanding - diluted   | 16,543,648   | 16,076,974     |
|   | =====        | =====          |

See accompanying notes.

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NOVOSTE CORPORATION  
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

|   | For the three months ended March 31,<br>2002 | 2001           |
|---|--|----------------|
|   | -----  | -----          |
| Cash flows from operating activities:   |  |                |
| Net income (loss)   | \$ 3,402,492                                 | \$ (6,628,567) |
| Adjustments to reconcile net income (loss) to net cash<br>Used by operating activities: |  |                |
| Depreciation and amortization   | 425,389                                      | 682,510        |
| Issuance of stock for services or compensation  | 196,875                                      | 237,254        |

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|  |               |              |
|--|---------------|--------------|
| Amortization of deferred compensation                | 50,938        | 178,006      |
| Amortization of radiation & transfer devices         | 1,582,186     | 435,167      |
| Provision for doubtful accounts                      | -             | 109,217      |
| Changes in assets and liabilities:                   |               |              |
| Accounts receivable                                  | (944,839)     | (4,322,114)  |
| Inventory  | (578,129)     | 319,562      |
| Prepaid expenses                                     | 12,959        | (93,106)     |
| Accounts payable                                     | 380,024       | 156,646      |
| Accrued expenses                                     | (4,413,553)   | (83,564)     |
| Deferred revenue                                     | (947,786)     | 942,996      |
| Other  | (33,865)      | (794,844)    |
|  | -----         | -----        |
| Net cash used by operations                          | (867,308)     | (8,861,262)  |
|  | -----         | -----        |
| Cash flow from investing activities:                 |               |              |
| Maturity (purchase) of short-term investments        | 9,782,220     | 5,038,530    |
| Purchase of property and equipment                   | (283,282)     | (1,072,228)  |
| Purchase of radiation and transfer devices           | (1,313,522)   | (3,500,409)  |
|  | =====         | =====        |
| Net cash provided by investing activities            | 8,185,416     | 465,893      |
|  | -----         | -----        |
| Cash flows from financing activities:                |               |              |
| Proceeds from issuance of common stock               | 359,369       | 373,409      |
| Proceeds from revolving line of credit               | 4,000,000     | -            |
| Repayment of capital lease obligations               | (64,068)      | (53,823)     |
|  | -----         | -----        |
| Net cash provided by financing activities            | 4,295,301     | 319,586      |
|  | -----         | -----        |
| Effect of exchange rate changes on cash              | 53,002        | 313,947      |
| Net increase (decrease) in cash and cash equivalents | 11,666,411    | (7,761,836)  |
| Cash and equivalents at beginning of period          | 5,878,286     | 26,512,398   |
|  | -----         | -----        |
| Cash and cash equivalents at end of period           | \$ 17,544,697 | \$18,750,562 |
|  | =====         | =====        |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW                 |               |              |
| Information:   |               |              |
| Cash paid for interest on capital lease obligation   | \$ 11,782     | \$ 23,306    |
| Non-cash investing and financing activities:         |               |              |
| Assets acquired under capital lease                  | \$ -          | 104,935      |

See accompanying notes.

NOVOSTE CORPORATION  
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 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 (consisting of normal recurring accruals) considered

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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 and in January 2000 in France. 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 that are classified as short-term (mature in more than 90 days but less than one year from the date of acquisition). Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation as of each balance sheet date.

The Company has classified all investments as available for sale. Available for sale securities are carried at fair value, with the unrealized gains and losses reported in a separate component of shareholders' equity if significant. Realized gains and losses are included in investment income and are determined on a specific identification basis.

### NOTE 3. ACCOUNTS RECEIVABLE

Accounts receivable at March 31, 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 customer's financial condition and generally does not require collateral. Management records estimates of expected credit losses and returns of product sold. Bad debt expense for the three-month period ended March 31, 2002 and 2001 amounted to \$0 and \$98,000, respectively.

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### 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:

|                 | March 31, 2002 | December 31, 2001 |
|-----------------|----------------|-------------------|
|                 | -----          | -----             |
| Raw Materials   | \$ 2,466,950   | \$ 1,971,347      |
| Work in Process | 1,042,650      | 811,406           |
| Finished Goods  | 790,888        | 963,680           |
|                 | -----          | -----             |
| Total           | \$ 4,300,488   | \$ 3,746,433      |
|                 | =====          | =====             |

### NOTE 5. RADIATION AND TRANSFER DEVICES

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The Company retains ownership of the radiation source trains (RSTs) and transfer devices (TDs). During 1999, the Company was the lessor of RSTs and TDs under annual sales-type lease agreements expiring through December 2000.

During the second quarter of 2000, the Company determined that based upon experience, testing and discussions with the FDA the estimated useful life of RSTs and TDs would exceed one year. Accordingly, the Company reclassified these assets from inventory to a long-term asset named, radiation and transfer devices. From the second quarter of 2000 through December 31, 2001, depreciation of the costs of these assets was recognized over their estimated useful lives (which was estimated at 18 months) using the straight-line method and began once the Beta-Cath(TM) System was placed into service. Concurrent with the change in estimated life, the RST and TD annual agreements to license the use of the radiation and transfer devices have been classified by the Company as operating leases.

During January 2002, the Company determined that, based upon new testing and experience, the estimated useful lives of RSTs and TDs are twelve months and three years, respectively. Accordingly, depreciation has been recognized over the new estimated lives starting at the beginning of the first quarter 2002. Depreciation begins when the Beta-Cath(TM) System is placed into service and annual lease agreements to license the Beta-Cath(TM) System are accounted for as operating leases. Depreciation of these assets is recorded in cost of sales. The effect of this change in estimate for the first quarter of 2002 is an increase in net income of \$940,980 or \$0.06 per common share on both a basic and diluted basis. At March 31, 2002, equipment with a cost of approximately \$15,975,000 before of accumulated depreciation of approximately \$6,802,000 were under operating leases. Approximately \$4,092,000 of radiation and transfer devices were available for lease at March 31, 2002. At March 31, 2002, lease payments receivable under these operating leases approximated \$954,000 and are recorded in accounts receivable. Radiation and transfer devices are stated at cost and are comprised of the following:

|                                | March 31, 2002 | December 31, 2001 |
|--------------------------------|----------------|-------------------|
|                                | -----          | -----             |
| Radiation and Transfer Devices | \$20,067,269   | \$18,753,747      |
| Less: Accumulated Depreciation | 6,801,577      | 5,219,391         |
|                                | -----          | -----             |
|                                | \$13,265,692   | \$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. During 2002, the Company charged approximately \$212,000 to compensation expense for such contributions. There was no compensation expense for the three-month period ended March 31, 2001. In addition, the Company advanced the officers a total of \$170,000 for related payroll taxes. This amount is reflected as a receivable 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 future. At March 31, 2002 and December 31, 2001, the receivable from officer's balance was \$314,497 and \$144,025, respectively.

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### NOTE 7. LINE OF CREDIT

In August 2001, the Company entered into a \$10 million accounts receivable revolving line of credit with a financial institution that matures in one year. At March 31, 2002 and December 31, 2001, the Company had borrowed \$4,000,000 and \$0, respectively. The Company may borrow an amount not to exceed the borrowing base as defined in the loan agreement. Interest 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%. At such time that the Company sustains three consecutive months of profitability, the rate decreases to the prime rate. The company granted a first priority security interest in substantially all assets of the Company. The loan agreement contains certain financial and nonfinancial covenants. The Company was not in violation of any of its loan covenants at March 31, 2002.

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.

### NOTE 8. BASIC AND DILUTED 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. Certain common stock equivalent shares are not included in the computation of diluted income (loss) per share where the effect would be antidilutive.

### NOTE 9. 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 income (loss) and long-lived assets by geographic area at March 31 are as follows:

#### Net sales

|      | United States<br>----- | Europe<br>----- | Rest of World<br>----- | Consolidated<br>----- |
|------|------------------------|-----------------|------------------------|-----------------------|
| 2002 | \$21,446,832           | \$1,284,746     | \$200,774              | \$22,932,352          |
| 2001 | 8,039,535              | 1,118,870       | 132,224                | 9,290,629             |

#### Net Income (Loss)

|      | United States<br>----- | Europe<br>----- | Rest of World<br>----- | Consolidated<br>----- |
|------|------------------------|-----------------|------------------------|-----------------------|
| 2002 | \$ 3,721,606           | \$ (49,074)     | \$ (270,040)           | \$ 3,402,492          |
| 2001 | (4,944,020)            | (1,592,344)     | (92,203)               | (6,628,567)           |

#### Long-lived assets



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|      | United States | Europe    | Rest of World | Consolidated |
|------|---------------|-----------|---------------|--------------|
|      | -----         | -----     | -----         | -----        |
| 2002 | \$23,966,736  | \$184,547 | -             | \$24,151,283 |
| 2001 | 17,064,529    | 383,188   | -             | 17,447,717   |

At March 31, 2002 and 2001, the Company's net assets outside of the United States, consisting principally of cash and cash equivalents, accounts receivable, inventory and office equipment, were approximately \$4,804,000 and \$4,965,000, respectively.

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NOTE 10.

The following table sets forth the computation of basic and diluted earnings per share:

|  | March 31, 2002 | Dece  |
|--|----------------|-------|
|  | -----          | ----- |
| Numerator:   |                |       |
| Net income (loss)  | \$ 3,402,492   |       |
| Denominator:   |                |       |
| Weighted-average shares outstanding                            | 16,273,595     |       |
| Unvested restricted stock outstanding                          | 6,587          |       |
|  | -----          |       |
| Denominator for basic earnings per share                       | 16,280,182     |       |
| Dilutive effect of stock options and invested restricted stock | 263,466        |       |
|  | -----          |       |
| Denominator for basic earnings per share                       | 16,543,648     |       |
| Net income (loss) per share                                    |                |       |
| Basic  | \$ 0.21        |       |
| Diluted  | \$ 0.21        |       |

NOTE 11. SHAREHOLDERS' EQUITY

For the three-month period ended March 31, 2002 changes in shareholders' equity consisted of the following:

|  |              |
|--|--------------|
| Shareholders' Equity at beginning of period  | \$64,727,641 |
|  | -----        |
| Proceeds from exercise of 56,375 stock options ranging from \$3.20 to \$6.65 per share | 359,369      |
| Deferred compensation relating to accelerated vesting of certain stock options         | 196,873      |
| Amortization of unearned compensation  | 50,938       |
| Comprehensive income (loss)  |              |
| Translation adjustment   | 96,490       |
| Net income   | 3,402,492    |
|  | -----        |
| Total comprehensive income   | 3,498,982    |

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Shareholders' Equity at March 31, 2002

-----  
\$68,833,803  
=====

### NOTE 12. RESTRUCTURING CHARGES

Restructuring charges of \$773,000 were recorded in 2001 primarily related to a reduction in workforce of thirteen employees located in Europe and six employees located in the United States in addition to termination of certain facility leases in Europe. The Company paid \$560,000 of the restructuring charges in the fourth quarter of 2001 related to severance payments and lease payments for closed facilities and recorded \$213,000 in accrued expenses related to severance agreements that were paid in the first quarter of 2002.

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

### FORWARD LOOKING STATEMENTS

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 the 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 section "Certain Factors That May Impact Future Operations." 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 revised any forward-looking statement, made by it or on its behalf, whether as a result of new information, future events, or otherwise.

### OVERVIEW

Novoste commenced operations as a medical device company in May 1992. Since 1994, we have devoted substantially all of our efforts to developing the Beta-Cath(TM) System. The Company commenced the active marketing of the Beta-Cath(TM) System in Europe in January 1999 for use in patients suffering from "in-stent restenosis", a condition in which coronary stents become clogged with new tissue growth. On November 3, 2000, Novoste received U.S. marketing approval for the 30-millimeter Beta-Cath(TM) System from the FDA and subsequently shipped its first commercial system on November 27, 2000. The number of commercial sites in the U.S. increased rapidly throughout 2001, and in the first quarter of 2002, the Company added over enty new sites.

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. At March 31, 2002 we

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had an accumulated deficit of approximately \$118.0 million. The Company experienced its first net operating profit in the third quarter of 2001. We expect to maintain an operating profit in 2002 as we continue to allocate resources to leverage our existing manufacturing operations, both internally and with outside vendors, 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. 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.

The Company also faces intense competition in the field of vascular brachytherapy with companies that have significantly greater capital resources than Novoste including Johnson & Johnson and Guidant. Both Johnson & Johnson and Guidant have introduced vascular brachytherapy products that compete with our Beta-Cath(TM) System. A new technology called drug-coated stents pose additional competitive threats in treating restenosis. We may not be able to sustain an acceptable level of market demand for the Beta-Cath(TM) System if this technology is successfully introduced. Failing to sustain our current level of demand could significantly reduce revenues and affect our ability to remain profitable.

### RESULTS OF OPERATIONS

Net income for the three months ended March 31, 2002 was \$3,402,492, or \$0.21 per share, as compared to a net loss of \$6,628,567 or (\$0.41) per share, for the three months ended March 31, 2001. The increase in net income for the three months ended March 31, 2002 compared to the year earlier period was primarily due to an increase in revenue from sales in the U.S. market from its commercial launch of the Beta-Cath(TM) System.

Net Sales. Net sales of \$22,932,352 were recognized in the three months ended  
-----

March 31, 2002 as compared to net revenue of \$9,290,629 for the three months ended March 31, 2001. Revenues recorded in the United States for the three-month period ended March 31, 2002 were \$21,446,832 as compared to \$8,039,535 for the same period ended March 31, 2001. The increase in revenues was primarily due to the addition of over 300 sites in the U.S. market since March 31, 2001 and the accompanying stocking orders for catheters in these new sites. Comparatively, international revenue increased 18.7% to \$1,485,520 compared to \$1,251,094. International sales increased from the prior year due to adding sites in other parts of the world. Non U.S. revenue has not risen at the same rate seen in the United States because of a lack of acceptance of vascular brachytherapy in Europe and no insurance reimbursement approval. The U.S. market received insurance reimbursement for the procedure in the second half of 2001 that contributed to the acceptance and growth in revenue in this market.

Cost of Sales. Cost of sales of \$6,678,121 were incurred in the three months  
-----

ended March 31, 2002 resulting in a gross margin of \$16,254,231 or 71% as compared to cost of sales of \$3,744,504 and a gross margin of \$5,546,124 or 60% for the three months ended March 31, 2001. The increase in gross margin on both an absolute and percentage basis is due to the higher sales and production volumes and improved production yields during 2002 over the same period in 2001. The Company expects gross margins to remain relatively stable during 2002 unless volume dramatically increases or decreases. 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 used in the Beta-Cath(TM) System.

Research and Development Expenses. Research and development expenses decreased  
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26% to \$2,658,926 for the three months ended March 31, 2002 from \$3,596,137 for the three months ended March 31, 2001. These decreases were primarily the result of decreased clinical trial activity related to the completion of pivotal trials and the elimination of costs associated with enrollments such as the costs of supplying product to clinical sites. The Company anticipates increasing research and development expenses in 2002 as it pursues product improvements and line extensions, some of which may require additional clinical trials.

Sales and Marketing Expenses. Sales and marketing expenses increased 13% to

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\$8,218,096 for the three months ended March 31, 2002 from \$7,286,234 for the three months ended March 31, 2001. These expenses increased primarily as the result of additional personnel, trade show, consulting and promotional literature costs associated with marketing the Company's product on a direct basis in the U.S. as we continued launch of the new Beta-Cath(TM) System in the U.S. However, these higher costs were offset by a decrease in the commission program for the U.S. sales force beginning in 2002. The Company expects sales and marketing expenses in 2002 to remain relatively consistent with 2001 expense.

General and Administrative Expenses. General and administrative expenses

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increased 15% to \$2,197,424 for the three months ended March 31, 2002 from \$1,910,700 for the three months March 31, 2001. The increase for this three month period was primarily the result of additional management personnel at higher salaries and the increase in infrastructure (accounting, information systems, human resources and benefits) to support the commercial launch of the Beta Cath System. The Company expects that at the current level of sales, general and administrative expenses will remain constant in 2002.

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Total Other Income. Total other income decreased 56% to \$272,707 for the three

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months ended March 31, 2002 from \$618,379 for the three months ended March 31, 2001. The decrease in interest income for the quarter was primarily due to the decrease in average cash equivalent and short-term investment balances that were used for operations combined with falling interest rates. In addition, interest expense increased as the Company leased additional computer equipment under capital lease obligations.

### LIQUIDITY AND CAPITAL RESOURCES

During the three months ended March 31, 2002 and 2001, the Company used cash to fund operations of \$0.9 million and \$8.9 million, respectively. The decrease in cash used by operating activities of \$8.0 million for 2002 over 2001 was primarily attributable to (i) \$10.0 million improvement from net loss to net income, (ii) \$3.4 million collection of accounts receivable, (iii) \$0.1 million increase in earnings from other assets, (iv) \$0.2 million provided by accounts payable, (v) \$0.8 million increase in other assets, (vi) \$0.1 million provided by prepaid expenses and (vii) \$0.5 million increase in earnings related to non-cash items, offset by (i) \$0.9 million used to fund the purchase of increased levels of inventory, (ii) \$4.3 million used for payment of accrued expenses and taxes withheld, and (iii) \$1.9 million decrease in unearned revenue related to revenue recognized on radiation and transfer devices.

Net cash provided by investing activities for the three months ended March 31, 2002 and 2001 was \$8.2 million and \$0.5 million, respectively. The \$7.7 million increase in cash provided in 2002 compared to 2001 was due to \$4.7 million in

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short-term investments that matured, \$0.8 million decrease in funds used to purchase of property and equipment, and \$2.2 million decrease in funds used to buy radiation and transfer devices.

The Company's financing activities include equity offerings, borrowings under a revolving credit facility and borrowings and repayments of capital leases. Financing activities for the three months ended March 31, 2002 and 2001 provided net cash of \$4.3 million and \$0.3 million, respectively. The change of \$4.0 million resulted primarily from borrowing under the accounts receivable revolving line of credit.

In August 2001, the Company entered into a \$10 million accounts receivable revolving line of credit with a financial institution (lender) that matures in one year. At March 31, 2002, the Company had borrowed \$4,000,000 to be used in operations. The Company may borrow an amount not to exceed the borrowing base as defined in the loan agreement. Interest 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%. At such time that the Company sustains three consecutive months of profitability, the rate decreases to the prime rate. The Company granted a first priority security interest in substantially all assets of the Company. Additionally, the loan agreement contains certain financial and non-financial covenants. The Company was not in violation of any of its loan covenants at March 31, 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 of the borrowing base minus (ii) the outstanding principal balance of the Advances and minus (iii) the Cash Management Sublimit as defined below; however, the face amount of 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 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 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 (the "Cash Management Services"). All amounts the Lender pays for any Cash Management Services will be treated as advances under the committed revolving line. The Company did not have any credit lines outstanding at March 31, 2002.

At March 31, 2002 the Company had commitments to purchase \$4.4 million in inventory components of the Beta-Cath(TM) System over the next year.

In addition, 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 over the period October 1, 1999 to mid 2002. The cost of this production line is estimated at \$4.0 million and is being paid by the Company as construction progresses. Through March 31, 2002, the Company has paid \$3.9 million towards this commitment.

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On June 20, 2001, the Company entered into a manufacturing and supply agreement (Agreement) with Bebig Isotopen-und Medizintechnik GmbH (Bebig), a German corporation, to manufacture and supply the Company with radioactive sealed Strontium-90 seed trains. The Agreement supercedes all prior agreements with Bebig and neither the Company nor Bebig have any rights or obligations under any of the previous agreements. During each calendar year under the four-year contract, the Company guarantees to pay to Bebig minimum annual payments. 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 one-year contract period. At December 31, 2001, the Company exceeded the annual guaranteed payment.

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 payment of \$5,000,000. Royalty fees to the physician aggregated \$208,670 and \$83,902 for the three months ended March 31, 2002 and 2001, respectively, and have been expensed in Cost of Sales.

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. 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 \$447,133 and \$205,836 for the three months ended March 31, 2002 and 2001, respectively, and have been expensed in Cost of Sales.

The Company's principal source of liquidity at March 31, 2002 consisted of cash, cash equivalents and short-term investments of \$39.4 million.

The Company had significant operating losses through the second quarter of 2001 and has been profitable for the remaining two quarters of 2001 and during the first quarter of 2002. The Company believes that existing cash and cash expected to be generated from a operations will be sufficient to meet its working capital, financing and capital expenditure requirements through at least 2002. The Company's future liquidity and capital requirements will depend upon numerous factors, including, 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

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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.

### CERTAIN FACTORS THAT MAY IMPACT FUTURE OPERATIONS

Dependence on the successful commercialization of 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 quarter 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. 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.

The Beta-Cath(TM) System received FDA approval for the 30-millimeter system on November 3, 2000; however, we may be unable to:

- manufacture the Beta-Cath(TM) System in commercial quantities at acceptable costs;

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The Beta-Cath(TM) System generated substantial revenue for Novoste in the first quarter 2002, however, in the future we may be unable 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 uncompetitive.

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### PROVISIONS DISCOURAGING A TAKEOVER

The amended and restated articles of incorporation provide for a classified board of directors, the existence of which could discourage attempts to acquire us. Furthermore, we are subject to the anti-takeover provisions of the Florida Business Corporation Act, the application of which would also have the effect of delaying or preventing a merger, takeover or other change of control of the Company and therefore could discourage attempts to acquire the Company.

### PRICE VOLATILITY AND FLUCTUATIONS IN OPERATING RESULTS

The market price of our common stock could decline below the public offering price. Specific factors relating to our business or broad market fluctuations may materially adversely affect the market price of our common stock. The trading price of our common stock could be subject to wide fluctuations in response to quarter-to-quarter variations in operating results, announcements of technological innovations, new products or clinical data announced by us or our

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competitors, governmental regulatory action, developments with respect to patents or proprietary rights, general conditions in the medical device or cardiovascular device industries, changes in earnings estimates by securities analysts, or other events or factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations, which have particularly affected the market prices of many medical device companies and which have often been unrelated to the operating performance of such companies. Our revenue or operating results in future quarters may be below the expectations of securities analysts and investors. In such an event, the price of our common stock would likely decline, perhaps substantially. During the three month period ended March 30, 2002, the closing price of our common stock ranged from a high of \$11.94 per share to a low of \$6.54 per share and ended that period at \$8.25 per share.

### PATENTS AND PROPRIETARY TECHNOLOGY

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 aspects of our Beta-Cath(TM) System. The United States Patent and Trademark Office has indicated that certain

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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 any protection to us because competitors may be able to design functionally equivalent devices that do not infringe this patent. It may also be reexamined, invalidated or circumvented. In addition, 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 have two versions of our delivery catheter: a "rapid exchange" catheter and an "over the wire" catheter. As a result of certain United States patents held by other device manufacturers covering "rapid exchange" catheters, we currently intend to sell the "over the wire" version of our delivery catheter in the United States. If further investigation reveals that we may sell a "rapid exchange" version in the United States without infringing the valid patent rights of others, we might decide to do so in the future. However, we cannot assure that we will be able to sell a "rapid exchange" version in the United States without a license of third party patent rights or that such a license would be available to us on favorable terms or at all.

COATED STENTS COULD RENDER VASCULAR BRACHTHERAPY GENERALLY OR THE BET-CATH(TM) SYSTEM IN PARTICULAR NONCOMPETITIVE OR OBSOLETE.



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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 may compete 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 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 are developing vascular brachytherapy devices.

Also on November 3, 2000, the FDA approved Johnson & Johnson's CHECKMATE(TM) System, a gamma radiation vascular brachytherapy device and on November 5, 2001 Guidant received FDA approval of its beta radiation device. Johnson & Johnson will compete directly with Novoste for market acceptance of vascular brachytherapy and has substantially greater capital resources and greater resources and experience at introducing new products than does Novoste. We may not be able to compete effectively against Johnson & Johnson.

Many of these same companies and others are researching coatings and treatments to coronary stents that could reduce restenosis and would possibly be more acceptable to a medical community already experienced at using stents. Recently, results from early non-randomized 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 approval for sale, could have a material adverse affect on Novoste's business. At least one competitor, Johnson & Johnson, could receive FDA approval as early as 2003.

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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. We may be unable to compete effectively against such competitors and other potential competitors in terms of manufacturing, marketing, distribution, sales and servicing.

Any product we develop that gains regulatory clearance or approval will have to compete for market acceptance and market share. An important factor in such competition may be the timing of market introduction of competitive products. Accordingly, we expect the relative speed with which we can develop products, gain regulatory approval and reimbursement acceptance and supply commercial quantities of the product to the market to be an important competitive factor.

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In addition, we believe that the primary competitive factors for products addressing restenosis include safety, efficacy, and ease of use, reliability, and suitability for use in cath labs, service and price. We also believe that physician relationships, especially relationships with leaders in the interventional cardiology and radiation oncology communities, are important competitive factors.

### GOVERNMENT REGULATION

#### United States

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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. The FDA regulates the clinical testing, manufacture, packaging, labeling, storage, distribution and promotion of medical devices. 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 approvals to market the Beta-Cath(TM) System for use with (1) further product design enhancements, such as varying lengths of the radiation source train or modifications to the catheter or (2) with a broader range of indications. The FDA may not act favorably or quickly on any of our submissions to the FDA. 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 pre-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

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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.

Our business involves the import, export, manufacture, distribution, use and storage of Strontium-90 (Strontium/Yttrium), the beta-emitting radioisotope

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utilized in the Beta-Cath(TM) System `s radiation source train. Accordingly, manufacture, distribution, use and disposal of the radioactive material used in the Beta-Cath(TM) System in the United States will be subject to federal, state and/or local rules relating to radioactive material. The State of Georgia Department of Natural Resources (DNR) issued a sealed source and device registration certificate for the Company's Beta-Cath(TM) System on August 4, 2000, allowing it to be listed on the Nuclear Regulatory Commission's Sealed Source and Device Registry. The DNR authorized Novoste to commercially distribute its radiation sources to licensed recipients in the United States with the issuance of a license allowing the manufacturing and distribution of the Beta-Cath(TM) System. In addition, we must comply with NRC, Georgia and United States Department of Transportation regulations on the labeling and packaging requirements for shipment of radiation sources to hospitals or other users of the Beta-Cath(TM) System.

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 will be required to amend their radiation licenses to include Strontium-90 prior to receiving and using our Beta-Cath(TM) System. Depending on the state that the hospital is located in, its license amendment will be processed at the DNR in agreement states, or by the 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 any of the foregoing approvals or any of those approvals are not obtained, our business, financial condition and results of operations could be materially adversely affected.

### INTERNATIONAL

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 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 March 31, 2001, the Company had \$18.8 million in cash equivalents with a weighted average interest rate of 5.29% and \$25.6 million in available for sale investments with a weighted average interest rate of 5.63%. At March 31, 2000 the Company had \$5.6 million in cash equivalents with a weighted average interest rate of 5.63% and \$6.1 million in available for sale investments with a weighted average interest rate of 6.05%. All investments mature, by policy, in one year or less.

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PART II. OTHER INFORMATION

Item 5. Other Information  
None

Item 6. Exhibits and Reports on Form 8-K  
None

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NOVOSTE CORPORATION

May 15, 2002

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Date

/s/ Edwin B. Cordell, Jr.

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

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