NOVOSTE CORP /FL/
Form 10-Q
May 15, 2001

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
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Exchange Act of 1934.

For the quarterly period ended March 31, 2001

___ 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)

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, 2001 there were 16,154,292 shares of the Registrant's Common Stock outstanding.

NOVOSTE CORPORATION

FORM 10-Q

INDEX

PART I. FINANCIAL INFORMATION P

Item 1. Consolidated Financial Statements

Consolidated Balance Sheets as of March 31, 2001 (unaudited) and December 31, 2000

Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2001 and 2000

Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2001 and 2000

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 5. Other Information

Item 6. Reports on Form 8-K

SIGNATURES

NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEETS

	March 31, 2001
	(Unaudited)
Assets	
Current assets:	
Cash and cash equivalents	$ 18,750,562
Short-term investments	25,616,907
Accounts receivable, net of allowance	8,535,692
Inventories	793,216
Prepaid expenses and other current assets	575,489
Total current assets	54,271,866

Property and equipment, net	7,751,079
Radiation and transfer devices, net	8,546,191
Other assets	1,150,447
Total assets	$ 71,719,583
Liabilities and Shareholders' Equity	
Current liabilities:	
Accounts payable	$ 3,564,701
Accrued expenses	5,289,423
Unearned revenue	1,516,017
Capital lease obligations	185,291
Total current liabilities	10,555,432
Long-term liabilities	
Capital lease obligations	475,152
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; 16,140,524 and 16,094,635 shares issued, respectively	161,405
Additional paid-in-capital	185,121,813
Accumulated other comprehensive income (loss)	(606,913)
Accumulated deficit	(122,903,254)
	61,773,051
Less treasury stock, 5,780 shares of common stock at cost	(23,840)
Accumulated other comprehensive loss	(1,060,212)
Total shareholders' equity	60,688,999
Total liabilities and shareholders' equity	$ 71,719,583

See accompanying notes.

NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended
	2001

Net sales and revenue	$ 9,290,629
Cost of sales	3,744,504
Gross margin	5,546,125
Operating expenses:	
Research and development	3,596,137
Sales and marketing	7,286,234
General and administrative	1,910,700
Total operating expenses	12,793,071
Loss from operations	(7,246,946)
Interest income, net	618,379
Net loss	$(6,628,567)
Net loss per share - basic and diluted	(0.41)
Weighted average shares outstanding - basic and diluted	16,076,974

See accompanying notes.

NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the three months ended Marc	
	2001	20
Cash flows from operating activities:		
Net loss	$(6,628,567)	$(7,1
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	672,190	3
Issuance of stock for services or compensation	237,254	1
Amortization of deferred compensation	178,006	2
Amortization of radiation & transfer devices	435,167	
Provision for doubtful accounts	97,992	
Changes in assets and liabilities:		

Accounts receivable	(4,163,903)	(
Inventory	458,471	(1
Prepaid expenses	(93,106)	(
Accounts payable	139,451	
Accrued expenses	(125,854)	(1,3
Unearned revenue	935,200	
Other	(721,243)	
Net cash used by operations	(8,578,942)	(8,0
Cash flow from investing activities:		
Maturity (purchase) of short-term investments	5,038,530	21,1
Purchase of property and equipment	(1,040,601)	(5
Purchase of radiation and transfer devices	(3,500,409)	
Net cash provided by investing activities	497,520	20,5
Cash flows from financing activities:		
Proceeds from issuance of common stock	373,409	49,3
Repayment of capital lease obligations	(53,823)	
Net cash provided by financing activities	319,586	49,3
Net (decrease) increase in cash and cash equivalents	(7,761,836)	61,8
Cash and equivalents at beginning of period	26,512,398	7,0
Cash and cash equivalents at end of period	$18,750,562	$68,9
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest on capital lease obligations	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, 2001

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 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, 2001. The accompanying consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2000 included in the Company's 2000 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. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Investments held-to-maturity are carried at amortized cost, adjusted for the amortization or accretion of premiums or discounts without recognition of gains or losses that are deemed to be temporary. Premiums and discounts are amortized or accreted over the life of the related instrument as an adjustment to yield using the straight-line method, which approximates the effective interest method. Interest income is recognized when earned.

Marketable equity securities and debt securities not classified as held-to-maturity are classified 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. The amortized cost of debt securities in this category is adjusted for amortization included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment 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 March 31, 2001 fair value approximated net book value for all short-term investments.

NOTE 3. ACCOUNTS RECEIVABLE

Accounts receivable at March 31, 2001 and December 31, 2000 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, 2001 amounted to $98,000. There was no bad debt expense recorded for the three month period ended March 31, 2000.

NOTE 4. INVENTORIES

Inventories are stated at the lower of cost or market and are comprised of the following:

	March 31, 2001	December 31, 2000
Raw Materials	$ 726,852	$ 777,819
Work in Process	54,935	218,958
Finished Goods	11,429	254,910
Total	$ 793,216	$ 1,251,687

NOTE 5. RADIATION AND TRANSFER DEVICES

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 has reclassified these assets from inventory to a long-term asset named, radiation and transfer devices. Depreciation of the costs of these assets will be over their estimated useful lives (currently estimated at 18 months) using the straight-line method and will begin once the Beta-Cath(TM) System is 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 are classified by the Company as operating leases. At March 31, 2001, equipment with a cost of approximately $2,892,000 before accumulated depreciation of approximately $567,000 were under operating leases. Approximately $6,221,000 of radiation and transfer devices were available for lease at March 31, 2001. At March 31, 2001, future minimum lease payments receivable under these operating leases approximated $720,000 and are recorded in accounts receivable.

NOTE 5. RADIATION AND TRANSFER DEVICES, continued

Radiation and transfer devices are stated at cost and are comprised of the following:

	March 31, 2001	December 31, 2000
Radiation and Transfer Devices	$ 9,113,173	$ 5,612,763
Less: Accumulated Depreciation	566,982	131,815
	$ 8,546,191	$ 5,480,948

NOTE 6. 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. Options to purchase shares of common stock are not included in the computation of diluted loss per share since the effect would be antidilutive.

NOTE 7. 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 Rest of World (Asia and South America).

The Company's net sales by geographic area are as follows:

	Three Months Ended March 31,			
	United States	Europe	Rest of World	Cons
2001	$8,039,535	$1,118,870	$132,224	
2000	0	832,909	13,137	

At March 3, 2001 and 2000, 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 $4,965,000 and $2,449,000, respectively.

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 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 12/31/00. 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. On November 3, 2000, Novoste received U.S. marketing approval for the 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.

Since our inception through March 31, 2001 we experienced significant losses in each period. The Company commenced the active marketing of the Beta-Cath(TM) System in Europe in January 1999. Although revenues are growing since the introduction of the Beta-Cath(TM) System in the U.S. market, we do not have experience in manufacturing, marketing or selling our products in quantities necessary for achieving profitability. At March 31, 2001, we had an accumulated deficit of approximately $122.9 million. We expect to continue to incur significant operating losses through at least 2001 as we allocate significant resources to increasing our manufacturing operations, both internally and with outside vendors, invest significantly in expanding our sales and marketing efforts in support of United States market development and increase our administrative activities to support our growth. 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.

While the Beta-Cath(TM) System has been approved by the FDA for use in patients suffering from in-stent restenosis, future clinical trials may not demonstrate the safety and effectiveness of other or different applications or utilizations of the product. Additionally, the hospitals and catheterization labs that will be our customers may not obtain necessary approvals for the Beta-Cath(TM) System from the state, federal or foreign governmental agencies that regulate the medical use of radiation. Our research and development efforts may not be successfully completed. Manufacturing of our products may be delayed by production problems or our vendors may be unable to produce sufficient quantities to meet our needs. We may not successfully introduce the Beta-Cath(TM) System or attract any significant level of market acceptance for the Beta-Cath(TM) System or any other product we develop. We may never achieve significant revenues

from sales of our Beta-Cath(TM) System and we may never achieve or sustain profitability.

RESULTS OF OPERATIONS

Net loss for the three months ended March 31, 2001 was $6,628,567, or ($.41) per share, as compared to $7,198,942 or ($.50) per share, for the three months ended March 31, 2000. The decrease in net loss for the three months ended March 31, 2001 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 and Revenue. Net sales and revenue of $9,290,629 were recognized in the three months ended March 31, 2001 as compared to net revenue of $846,046 for the three months ended March 31, 2000. Net sales and revenue increased due the FDA approval of the Beta-Cath(TM) System in the U.S. and the initial, first full quarter of sales in the U.S. The Company expects net sales and revenue to increase in the future as direct distribution is expanded in the U.S.

Net sales and revenue generated in the United States for the three months ended March 31, 2001 totaled 86.5% of total revenue. In the same period ending March 31, 2000, no revenues were reported from the domestic market. There were no individual customers or distributors that represented more than 5% of net sales and revenue in the first quarter ended March 31, 2001. Approximately 90% of revenue was generated by catheter sales during the first quarter 2001 compared to 83.5% in first quarter 2000. The remainder of revenue in the first quarter 2001 was generated from the sales of license and lease agreements to use the radiation source trains and transfer devices included in the Beta-Cath(TM) System, Revenue from these license and lease agreements in 2001 are recognized over the term of the agreement, typically 18 months. Revenue recognized in the first quarter of 2000 was accounted for properly as a sales-type lease and, accordingly, revenue and the related cost of sales were recognized upon shipment.

Cost of Sales. Cost of sales of $3,744,504 were incurred in the three months
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ended March 31, 2001 as compared to cost of sales of $753,380 for the three months ended March 31, 2000. The Company expects cost of sales to increase as sales activities in the U.S. continue to grow. However, cost of sales will continue to grow at a slower pace than revenue as the manufacturing facility continues to utilize capacity of the current plant and therefore increase gross margin.

Research and Development Expenses. Research and development expenses decreased
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20% to $3,596,137 for the three months ended March 31, 2001 from $4,475,540 for the three months ended March 31, 2000. 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. However, the Company expects research and development expenses to increase throughout the year in anticipation of new clinical trial activity.

Sales and Marketing Expenses. Sales and marketing expenses increased 208% to
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$7,286,234 for the three months ended March 31, 2001 from $2,369,504 for the three months ended March 31, 2000. These increases were primarily the result of higher 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 launched the new Beta-Cath(TM) System in the U.S. The Company expects sales and marketing expenses to increase significantly in the future as direct distribution is expanded in the U.S.

General and Administrative Expenses. General and administrative expenses
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increased 82% to $1,910,700 for the three months ended March 31, 2001 from $1,047,501 for the three months March 31, 2000. The increase for the three month period was primarily the result of additional management personnel at higher salaries and information systems costs. The Company expects general and administrative expenses to increase in the future in support of a higher level of operations.

Interest Income. Net interest income increased 7% to $642,918 for the three
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months ended March 31, 2001 from $600,937 for the three months ended March 31, 2000. The increase in interest income for the quarter was primarily due to the increase in average cash equivalent and short-term investment balances.

LIQUIDITY AND CAPITAL RESOURCES

During the three months ended March 31, 2001 and 2000, the Company used cash to fund operations of $8.6 million and $8.1 million, respectively. At March 31, 2001, the Company had commitments to purchase $7.4 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 August 2001. 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, 2001, the Company has paid $2,377,000 towards this commitment. Because of the development, manufacturing scale-up and commercialization of the Beta-Cath(TM) System, Novoste's future cash needs for operating and investing activities are anticipated to be higher than historical levels subject to the factors discussed below.

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 $83,902 and $7,083 for the three months ended March 31, 2001 and 2000, 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 $205,836 and $17,052 for the three months ended March 31, 2001 and 2000, respectively, and have been expensed in Cost of Sales.

The Company's principal source of liquidity at March 31, 2001 consisted of cash, cash equivalents and short-term investments of $44.4 million. The Company did not have any credit lines available or outstanding borrowings at March 31, 2001.

The Company anticipates that its operating losses will continue through at least 2001 as it expends

substantial resources to expand sales and marketing activities. We believe that our existing capital resources will be sufficient to fund the Company through the second quarter of 2002, but those resources may prove insufficient. The Company's future liquidity and capital requirements will depend upon numerous factors, including, among others: market acceptance and demand for its products; the resources required to maintain a direct sales force in the United States and

in the larger markets of Europe, develop distributors internationally, and to expand manufacturing capacity; the resources the Company devotes to the development, manufacture and marketing of its products; the receipt of and the time required to obtain additional regulatory clearances and approvals; the resources required to gain such approvals; 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 offerings 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 OPERATONS

We depend on the successful development and commercialization of the Beta-Cath (TM) System.

We have just recently begun to commercialize the Beta-Cath(TM) System in the United States and our distribution system in Europe and certain Asian countries are still being developed. We anticipate that for the foreseeable future we will be solely dependent on the successful development and 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;

- gain any significant degree of market acceptance of the Beta-Cath(TM) System among physicians, patients and/or health care payors;

- broaden the Beta-Cath(TM) system marketability by obtaining approval for additional applications of our product; or

- 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 other competitive technologies.

Because the Beta-Cath(TM) System is our sole near-term product focus, we could be required to cease operations if it is not successfully commercialized.

We have limited operating history; we have a history of losses and expect future losses through at least the year 2001.

We have a limited history of operations. Since our inception in May 1992, we have been primarily engaged in developing and testing our Beta-Cath(TM) System. We have generated only limited revenue and do not have experience in manufacturing, marketing or selling our products in quantities necessary for achieving profitability.

At March 31, 2001, we had accumulated a deficit of approximately $122.9 million since our inception in 1992. The commercialization of the Beta-Cath(TM) System and other new products, if any, will require substantial additional development, clinical, regulatory, manufacturing, sales and marketing and other expenditures. We expect our operating losses to continue through at least 2001 as we continue to expand our product development, clinical trials and marketing efforts. We may

never:

- achieve commercial success in the sale of the Beta-Cath(TM) System or any other product in any countries in which we have received the necessary governmental approvals to market these products; or

- achieve or sustain profitability.

United States Pre-Market Approvals

On November 3, 2000, we received marketing approval from the FDA for the Beta-Cath(TM) System. This approval limits our ability to promote the Beta-Cath(TM) System for use with patients who are being treated for "in-stent" restenosis in a single coronary artery with a 30-millimeter radiation source train. In order to market the Beth-Cath(TM) System with a 40-millimeter radiation source train, we will likely be required to demonstrate to the FDA through the START 40 Trial that the Beth-Cath(TM) System with the longer source train is safe and effective. In order to market the Beta-Cath(TM) System for a broader range of patients, we may seek to expand the indications for which the Beta-Cath(TM) System can be marketed to, for example, patients undergoing balloon angioplasty of previously untreated (de novo) lesions.

In order 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, including stand alone balloon angioplasty or previously untreated (de novo) lesions we will likely be required to demonstrate to the FDA through additional clinical trials that the Beta-Cath(TM) System is safe and effective with such product design enhancement(s) or in treating a broader range of indications and the FDA must approve a pre-market approval application, application amendment or application supplement covering the product design enhancement(s) or the broader range of indications for the device. Even if we were to receive FDA approval based on the results of the Beta-Cath(TM) System Trial, we would be limited under that approval to promoting the Beta-Cath(TM) System for use with patients who are being treated for one lesion in a single coronary artery following stand-alone balloon angioplasty.

Foreign Pre-Market Approvals

Sales of the Beta-Cath(TM) System outside the United States are subject to regulatory requirements that vary widely from country to country but generally include pre-marketing governmental approval. The time required to obtain approval for sale in foreign countries may be longer or shorter than required for FDA approval, and the requirements for the conduct of clinical trials, marketing authorization, pricing and reimbursement differ from those in the United States. Moreover, the export of medical devices from the United States must be in compliance with FDA regulations. In August 1998 we qualified to apply CE marking to the Beta-Cath(TM) System, a requirement necessary to sell our device in most of Western Europe. We are subject to continuing audit and reporting requirements related to this marking. We may be delayed or precluded from marketing the Beta-Cath(TM) System in other foreign countries. Foreign pre-market and other regulatory approvals of the Beta-Cath(TM) System, if granted, may include significant limitations on the indicated uses for which the device may be marketed.

Approvals to Use, Handle and Transfer Radioactive Materials

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. 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. Recently, 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, allowing it to be listed on the Nuclear Regulatory Commission's Sealed Source and Device Registry. The Company anticipates that the DNR will authorize Novoste to commercially distribute our radiation sources to licensed recipients in the United States. 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. Further, hospitals and/or physicians in the United States may be required to amend their radiation licenses to hold, handle and use Strontium-90 prior to receiving and using our Beta-Cath(TM) System.

LIMITED MANUFACTURING EXPERIENCE; SCALE-UP RISK

To date, we have not yet successfully commercialized the Beta-Cath(TM) System, and our manufacturing activities have consisted of producing small quantities of our products for use in clinical trials and our initial product launch in Europe and the United States. To achieve profitability, the Beta-Cath(TM) System must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. Production in commercial quantities will require us to expand our manufacturing capabilities and to hire and train additional personnel. We have no experience in manufacturing our products in commercial quantities. We may encounter difficulties in scaling up production, including problems involving production yields, quality control and assurance, component supply and shortages of qualified personnel. Difficulties encountered in manufacturing scale up could have a material adverse effect on our business, financial condition and results of operations. We cannot assure that future-manufacturing difficulties, which could have a material adverse effect on our business, financial condition and results of operations, will not occur.

OTHER 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 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, 2001, the closing price of our common stock ranged from a high of $38.875 per share to a low of $14.00 per share and ended that period at $17.5625 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 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 received a letter from NeoCardia, L.L.C., dated July 7, 1995, in which NeoCardia notified us that it was the exclusive licensee of United States Patent No. 5,199,939, or the Dake patent, and requested that we confirm that our products did not infringe the claims of the Dake patent. On August 22, 1995 our patent counsel responded on our behalf that we did not infringe the Dake patent.

The United States Patent and Trademark Office later reexamined the Dake patent. In the reexamination proceeding some of the patent claims were amended and new claims were added. We have concluded, based upon advice of patent counsel, that our Beta-Cath(TM) System does not infringe any claim of the Dake patent as reexamined.

In May 1997 Guidant acquired NeoCardia together with the rights under the Dake patent. Guidant is attempting to develop and commercialize products that may compete with the Beta-Cath(TM) System and has significantly greater capital resources than the Company. Guidant may sue for patent infringement in an attempt to obtain damages from us and/or injunctive relief restraining us from commercializing the Beta-Cath(TM) System in the United States. While the Company does not believe such an action would have merit, if Guidant were successful in any such litigation, we might be required to obtain a license from Guidant under the Dake patent to market the Beta-Cath(TM) System in the United States, if such license were available, or be prohibited from selling the Beta-Cath(TM) System in the United States. Any of these actions could have a material adverse effect on our business, financial condition and results of operations, or could result in cessation of our business.

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.

COMPETITION; RAPID TECHNOLOGICAL CHANGE

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 2000. 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. 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. Extensive clinical trials will need to be completed in order to confirm these results, however, positive information from these trials could have a negative impact on the ultimate acceptability of vascular brachytherapy and the Company's stock price.

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. 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

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.

On November 3, 2000, the FDA approved our pre-market approval (PMA) application for the Beta-Cath(TM) System. This approval limits our ability to promote the Beta-Cath(TM) System to use with patients who are being treated for "in-stent" restenosis in a single coronary artery with a 30-millimeter radiation source train. In order to market the Beta-Cath(TM) System with a 40-millimeter radiation source train, we submitted a PMA supplement to the FDA on December 27, 2000 and included the data from our START 40 trial in order to demonstrate safety and efficacy. The PMA supplement is currently under review with the FDA. In order 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, we will likely be required to demonstrate to the FDA through additional clinical trials that the Beta-Cath(TM) System is safe and effective with such product design enhancement(s) or in treating a broader range of indications and the FDA must approve a pre-market approval application, application amendment or application supplement covering the product design enhancement(s) or the broader range of indications for the device.

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. We do not anticipate pre-market approval for the supplement application for the 40mm Beta-Cath(TM) System to treat in-stent restenosis until the second quarter of 2001, if at all. 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 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 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 weigted 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.

Foreign Currency Risk

International revenues from the Company's foreign direct sales and distributor sales comprised 11% of total revenues for the three month period ended March 31, 2001. With the exception of the Australian and New Zealand distributors, sales are denominated in Euros. The Company experienced an immaterial amount of transaction gains and losses through the three month period ending March 31, 2001. The Company is also exposed to foreign exchange rate fluctuations as the financial results of its Belgian, German, Dutch, and French subsidiaries are translated into U.S. dollars in consolidation. As exchange rates vary, these results, when translated, may vary from expectations and adversely impact overall expected profitability. The net effect of foreign exchange rate fluctuations on the Company during the three month period ending March 31, 2001 was not material.

PART II. OTHER INFORMATION

Item 5. Other Information

Effective April 24, 2001, David C. Field joined the company as Vice President, of Peripheral Business.

Item 6. Reports on Form 8-K

(a) The Company filed a Form 8-K on January 30, 2001, stating that on January 29, 2001 it had issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2000.

(b) The Company filed a Form 8-K on March 19, 2001, stating that on March 18, 2001, the Registrant announced the results of the Beta-Cath System trial.

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, 2001	/s/ Edwin B. Cordell, Jr.
Date	Edwin B. Cordell, Jr. Vice President - Finance, Chief Financial Officer (Principal Financial & Accounting Officer)