NOVOSTE CORP /FL/
Form 10-Q
November 14, 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 Exchange Act of 1934.

For the quarterly period ended September 30, 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 November 1, 2001 there were 16,231,569 shares of the Registrant's Common Stock outstanding.

NOVOSTE CORPORATION

FORM 10-Q

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NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEETS

	September 30, 2001 (Unaudited)
Assets	
Current assets:	
Cash and cash equivalents	$ 14,377,259
Short-term investments	22,134,142
Accounts receivable, net of allowance	13,923,403
Inventories	2,682,649
Prepaid expenses and other current assets	1,099,769
Total current assets	54,217,222
Property and equipment, net	8,951,527
Radiation and transfer devices, net	12,100,439
Other assets	1,498,348
Total assets	$ 76,767,536

Liabilities and Shareholders' Equity	
Current liabilities:	
Accounts payable	$ 2,976,790
Accrued expenses	8,227,905
Unearned revenue	3,541,659
Capital lease obligations	62,011
Total current liabilities	14,808,365
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; 16,223,649 and 16,094,635 shares issued, respectively	162,236
Additional paid-in-capital	187,104,201
Accumulated other comprehensive income (loss)	(311,591)
Accumulated deficit	(124,113,621)
	62,841,225
Less treasury stock, 5,780 shares of common stock at cost	(23,840)
Unearned compensation	(1,333,366)
Total shareholders' equity	61,484,019
Total liabilities and shareholders' equity	$ 76,767,536

See accompanying notes.

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NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended September 30,		Nine mo
	2001	2000	
Net Sales	$ 20,916,639	$ 1,445,527	$47,4
Cost of Sales	5,118,949	977,146	14,5
Gross Margin	15,797,690	468,381	32,9
Operating expenses			
Research and Development	2,941,372	5,248,267	10,2
Sales and Marketing	8,990,636	3,171,584	25,4
General and Administrative	2,252,761	1,855,862	6,7
Total operating expenses	14,184,769	10,275,713	42,4

Income/(Loss) from operations	1,612,921	(9,807,332)	(9,5
Interest Income	492,933	1,108,202	1,7
Interest Expense	19,613	5,652	
	473,320	1,102,550	1,6
Net income/(loss)	$ 2,086,241	$(8,704,782)	$(7,8
Basic earnings per share	$ 0.13	$ (0.54)	$
Weighted average shares outstanding - basic	16,188,275	16,005,921	16,1
Weighted average shares outstanding - diluted	16,418,391	16,005,921	16,1

See accompanying notes.

NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the nine months ended September 2001	2000
Cash flows from operating activities:		
Net loss	$ (7,383,934)	$ (23,032,8
Adjustments to reconcile net loss to net cash used by Operating activities:		
Depreciation and amortization	1,770,425	961,6
Issuance of stock for services or compensation	155,246	379,6
Amortization of deferred compensation	826,222	470,8
Amortization of radiation & transfer devices	3,077,099	
Provision for doubtful accounts	587,920	150,0
Changes in assets and liabilities:		
Accounts receivable	(10,041,542)	(1,387,3
Inventory	(1,430,962)	1,918,7
Prepaid expenses	(617,386)	(942,6
Accounts payable	(448,460)	1,729,7
Accrued expenses	2,812,628	(438,5
Unearned revenue	2,960,842	300,4
Other	(793,328)	(379,8
Net cash used by operations	(8,980,230)	(20,269,7

Cash flow from investing activities:		
Maturity of short-term investments	8,521,294	12,602,0
Purchase of property and equipment	(3,339,284)	(2,793,0
Purchase of radiation and transfer devices	(9,696,590)	(3,487,0
Net cash (used) provided by investing activities	(4,514,580)	6,321,9
Cash flows from financing activities:		
Proceeds from issuance of common stock	1,517,267	55,948,3
Repayment of capital lease obligations	(177,103)	
Net cash provided by financing activities	1,340,164	55,948,3
Effect of exchange rates on cash and cash equivalents	19,507	105,1
Net (decrease) increase in cash and cash equivalents	(12,135,139)	42,105,7
Cash and equivalents at beginning of period	26,512,398	7,091,0
Cash and cash equivalents at end of period	$ 14,377,259	$ 49,196,7
SUPPLEMENTAL DISCLOSURE OF CASH FLOW Information:		
Cash paid for interest on capital lease obligation	$ (45,027)	$
Non-cash investing and financing activities:		
Assets acquired under capital lease	$ 105,000	$

See accompanying notes.

NOVOSTE CORPORATION
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 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

The Company maintains cash equivalents and investments in several large well-capitalized financial institutions. The Company's investment policy does not allow investment in any debt securities rated less than "investment-grade" by national racings services. Cash equivalents are comprised of certain highly liquid investments with maturities of less than three months. In addition to cash equivalents, the Company has investments in commercial paper and certificates of deposit that are classified as short-term (mature in more than 90 days but less than one year).

Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. These investments are accounted for in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, Accounting for Certain Investments in Debt and Equity Securities ("SFAS 115"). The Company has classified all short and long-term 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 stockholder's 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 September 30, 2001 and December 31, 2000 include receivables due from product sales and amounts due under lease arrangements relating to radiation and transfer devices (see Note 5. Radiation and Transfer Devices). The carrying amounts reported in the consolidated balance sheets for accounts receivable approximate their fair value. The Company performs periodic credit evaluations of its 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 nine month period ended September 30, 2001 amounted to approximately $12,000. There was no bad debt expense recorded for the nine month period ended September 30, 2000.

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:

	September 30, 2001	December 31, 2000
Raw Materials	$1,576,722	$ 777,819
Work in Process	320,398	218,958
Finished Goods	785,529	254,910
Total	$2,682,649	$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, which is included in cost of sales, 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 September 30, 2001, equipment with a cost of approximately $10,509,000 before accumulated depreciation of approximately $3,077,000 was under operating leases. Approximately $4,669,000 of radiation and transfer devices were available for lease at September 30, 2001. At September 30, 2001, amounts receivable under these operating leases approximated $1,705,000 and are recorded in accounts receivable. Radiation and transfer devices are stated at cost and are comprised of the following:

	September 30, 2001	December 31, 2000
Radiation and Transfer Devices	$ 15,177,538	$ 5,612,763
Less: Accumulated Depreciation	3,077,099	131,815
Total	$ 12,100,439	$ 5,480,948

NOTE 6. 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 September 30, 2001, there were no outstanding borrowings. The Company may borrow an amount not to exceed the borrowing base of 80% of eligible accounts receivable 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 Company must meet certain financial covenants related to maintaining a minimum tangible net worth and quick ratio. The Company was not in violation of any of its loan covenants at September 30, 2001.

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 the Rest of World (Asia and South America)

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

	United States	Europe	Rest of World	Consolidated
2001	$43,466,425	$3,527,056	$504,493	$47,497,974
2000	462,772	2,778,233	342,570	3,583,575

At September 30, 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 $6,529,000 and $3,061,000, respectively.

NOTE 8. EARNINGS PER SHARE

The computation, presentation and disclosure requirements for earnings per share are presented in accordance with Statement of Financial Accounting Standards ("SFAS") No. 128, "Earnings per Share." Basic earnings per common share is computed by dividing net income by the weighted average number of common shares outstanding during each period. Diluted earnings per common share assumes exercise of outstanding stock options and vesting of restricted stock when the effects of such assumptions are dilutive.

The following table sets forth the computation of basic and diluted earnings per share for the three-month period ended September 30, 2001:

Weighted average number of common shares outstanding-Basic	16,188,275
Dilutive effect of:	
Restricted stock	18,908
Stock options	211,208
Weighted average number of common and common equivalent shares outstanding-Diluted	16,418,391

Common equivalent shares are antidilutive for the nine-month period ended September 30, 2001 and for 2000.

NOTE 9. SHAREHOLDERS' EQUITY

For the three and nine month period ended September 30, 2001 changes in shareholders' equity consisted of the following:

Shareholders' Equity at beginning of period	$ 57,639,304	$ 67,042,119
Exercise of 21,562 and 92,238 stock options ranging from $3.20 to $27.00 per share	210,079	1,095,445
Proceeds from issuance of stock under employee stock purchase plan, 18,873 shares on 4/2/01 at $14.93 pre share and 17,903 shares on 7/2/01 at $14.93 per share	267,258	548,996
Other equity transactions	18,000	18,000
Amortization of unearned compensation	238,002	479,071
Comprehensive loss:		
Translation adjustment	1,025,135	(217,901)
Net income/(loss)	2,086,241	(7,838,934)

Total comprehensive income (loss)	3,111,376	(8,056,835)
Shareholders' Equity at September 30, 2001	$ 61,484,019	$ 61,484,019

During April 2001, the Company granted 101,000 stock options to certain officers of the Company. Based quoted market value per share at the grant date, the value of the shares has been recorded as unearned compensation in the amount of $839,000. Such unearned compensation is being amortized to compensation expense over the vesting period of the awards.

NOTE 10. SUBSEQUENT EVENT

Subsequent to September 30, 2001 the Company announced a restructuring of its operations outside the United States. The restructuring is intended to reduce operating expenses in the future by consolidating certain functions and offices in Europe. The Company expects restructuring charges of approximately $1 million to be incurred in the fourth quarter 2001.

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 December 31, 2000. The Company does not undertake any obligations to update or revise 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. On November 3, 2000, Novoste received U.S. marketing approval for the 30-millimeter Beta-Cath(TM) System from the FDA for use in patients suffering from "in-stent restenosis", a condition in which coronary stents become clogged with new tissue growth. On September 18, 2001 Novoste received US marketing approval for the 40-millimeter Beta-Cath(TM) System from the FDA. 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.

Since our inception through June 30, 2001 we experienced significant losses in each period. For the quarter ended September 30, 2001, the Company experienced its first net operating profit. At September 30, 2001, we had an accumulated deficit of approximately $124.1 million. We expect to maintain an operating profit in the fourth quarter of 2001 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 or even decline 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. New technologies under development by companies that have significantly greater resources than Novoste, including coated stents being developed by Johnson & Johnson, Guidant, Cook and Boston Scientific, pose additional competitive threats in treating restenosis. We may not successfully sustain an acceptable level of market demand for Beta-Cath(TM) System or any other product we develop. We may be unable to sustain significant revenues from sales of our Beta-Cath(TM) System and we may not be able to sustain profitability.

RESULTS OF OPERATIONS

Net income for the three months ended September 30, 2001 was $2,086,241 or $.13 per share, as compared to net loss of $8,704,782 or ($.54) per share, for the three months ended September 30, 2000. Net loss for the nine months ended September 30, 2001 was $7,838,934, or ($.49) per share, as compared to $23,032,857 or ($1.50) per share, for the nine months ended September 30, 2000. The increase/decrease in net income/(loss) for the three and nine months ended September 30, 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. Net sales of $20,916,638 and $47,497,974 were recognized in the three and nine months ended September 30, 2001 as compared to net sales of $1,445,527 and $3,583,575 for the three and nine months ended September 30, 2000. Net sales increased due to the FDA approval of the Beta-Cath(TM) System in the U.S. and the initial, first three full quarters of sales in the U.S. Net sales in the United States for the three and nine months ended September 30, 2001 were $19,437,626 and $43,466,425. The Company added over 70 sites in the U.S. for the three months ended September 30, 2001 for a total of over 290 new sites for the year. All sales in the 2000 three and nine month periods were due to sales made in Europe. Comparatively, internationally the Company recognized net sales of $1,500,261 and $4,031,549 in the three and nine months ended September 30, 2001. Sales remained relatively flat in Europe due to lack of acceptance of vascular brachytherapy in Europe and lack of approval for insurance reimbursement for vascular brachytherapy. However, international sales increased from the prior year due to adding sites in other parts of the world.

Cost of Sales. Cost of sales for the three months ended September 30, 2001 were $5,118,949 resulting in a gross margin of 75.5%, compared to cost of sales of $977,146 and gross margin of 32.4% for the same period of 2000. Cost of sales were $14,589,293 for the nine months ended September 30, 2001 resulting in a

gross margin of 69.3% as compared to cost of sales of $2,594,894 and a gross margin of 27.6% for the nine months ended September 30, 2000. 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. Cost of sales is expected to continue to grow at a slower pace than sales 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 44% to $2,941,372 for the three months ended September 30, 2001 from $5,248,267 for the three months ended September 30, 2000. For the nine months ended September 30, 2001 research and development expenses decreased 27% to $10,261,939 from $13,974,188 for the same period a year earlier. 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 from third quarter 2001 in anticipation of new clinical trial activity.

Sales and Marketing Expenses. Sales and marketing expenses increased 183% to $8,990,636 for the three months ended June 30, 2001 from $3,171,584 for the three months ended September 30, 2000. For the nine months ended September 30, 2001 sales and marketing expenses were $25,425,965 as compared to $8,528,790 for the nine months ended September 30, 2000, an increase of 198%. These increases were primarily the result of additional sales and customer support personnel, training, trade show, consulting and promotional literature costs associated with marketing the Company's product on a direct basis in the U.S. as the Company launched the new Beta-Cath(TM) System in the U.S. Significant resources were expended in launching the Beta-Cath(TM) System in the U.S. The Company expects that future sales and marketing expenses may grow at a slower pace than net sales, or may even decline.

General and Administrative Expenses. General and administrative expenses for the three and nine months ended September 30, 2001 were $2,252,761 and $6,739,757 as compared to the three and nine months ended September 30, 2000 of $1,855,862 and $4,271,017, an increase of 21% and 58%, respectively. The increase for the three and nine-month period was primarily the result of additional management personnel at higher salaries and information systems costs in support of building the infrastructure of the Company. The Company expects general and administrative expenses to remain constant in the future.
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Interest Income. Net interest income decreased 57% to $473,320 for the three months ended September 30, 2001 from $1,102,550 for the three months ended September 30, 2000. Net interest income decreased 39% to $1,680,046 for the nine months ended September 30, 2001 from $2,752,457 for the nine months ended September 30, 2000. The decrease in interest income for the three and nine months was primarily due to the decrease in average cash equivalent and short-term investment balances used in operations combined with falling interest rates.

LIQUIDITY AND CAPITAL RESOURCES

During the nine months ended September 30, 2001 and 2000, the Company used cash to fund operations of $9.0 million and $20.2 million, respectively. The decrease in cash used by operating activities of $11.2 million for 2001 over

2000 was primarily attributable to (i) $15.2 million decrease in net loss, (ii) $4.5 million increase in earnings related to non-cash items, (iii) $.3 million increase in prepaid expenses, (iv) $3.3 million provided by accrued expenses, and (v) $2.7 million increase in unearned revenue related to revenue recognized on radiation and transfer devices offset by (i) $8.7 million funding of accounts receivable due to the growth in sales of the Beta-Cath(TM) System related to the initial market launch in the US, (ii) $3.3 million used to fund the purchase of increased levels of inventory, (iii) $2.2 million used for payment of accounts payable, and (iv) $.5 million increase in other assets.

Net cash used by investing activities for the nine months ended September 30, 2001 was $4.5 million and net cash provided by investing activities for the nine months ended September 30, 2000 was $6.3 million. The $10.8 million increase in cash used in 2001 compared to 2000 was due $4.1 million in short-term investments that matured, $.5 million increase in the purchase of property and equipment, and $6.2 million used to buy radiation and transfer devices related to the increase in demand for our Beta-Cath(TM) System.

Our financing activities include equity offerings and borrowings and repayments of capital leases. Financing activities for the nine months ended September 30, 2001 and 2000 provided net cash of $1.3 million and $55.9 million, respectively. The change of $54.6 million resulted primarily from receiving net proceeds of $49.0 million in April 2000 for a private placement offering plus $6.9 million from the exercise of stock options during the nine months ended September 30, 2000 and $1.7 million from the exercise of stock options during the same period in 2001. In addition, the company repaid $.2 million for capital leases of computer equipment.

On April 7, 2000 we completed a private placement offering, in which we sold 1,463,500 shares of our common stock at $35.00 per share. The placement raised net proceeds of approximately $49 million, of which $5 million was received during the second quarter. After the offering, we had 15.85 million shares of common stock outstanding. The Company also received approximately $1.6 million for the quarter and $6.9 million for the nine months ended September 30, 2000 from the exercise of stock options. In 2001, the Company received $.8 million from the exercise of stock options for the quarter and $1.7 million for the nine months ended September 30, 3001.

At September 30, 2001, the Company had commitments to purchase $7.1 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 January 2002. The cost of this production line is estimated at $4.0 million and is being paid by the Company as construction progresses. Through September 30, 2001, the Company has paid $3.1 million towards this commitment.

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 $429,257 and $29,472 for the nine months ended September 30, 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 $998,278 and $69,190 for the nine months ended September 30, 2001 and 2000, respectively, and have been expensed in Cost of Sales.

The Company's principal source of liquidity at September 30, 2001 consisted of cash, cash equivalents and short-term investments of $36.5 million.

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 September 30, 2001, there were no outstanding borrowings. The Company may borrow an amount not to exceed the borrowing base of 80% of eligible accounts receivable 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 Company must meet certain financial covenants related to maintaining a minimum tangible net worth and quick ratio. The Company was not in violation of any of its loan covenants at September 30, 2001.

The Company had significant operating losses through the second quarter of 2001 and had its first profitable quarter in the third quarter 2001. We believe that our existing capital resources will be sufficient to fund the Company until it reaches a positive operating cash flow. The Company expects that given its current rate of revenue growth, it will continue to have sufficient cash flow to support growth of the business in the US and the Company also feels it will have sufficient cash reserves until it is able to sustain a positive cash flow in early 2002. 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 continue 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.

Subsequent to September 30, 2001 the Company announced a restructuring of its operations outside the United States. The restructuring is intended to reduce operating expenses in the future by consolidating certain functions and offices in Europe. The Company expects restructuring charges of approximately $1 million to be incurred in the fourth quarter 2001.

The Company is evaluating both internally and externally developed strategic opportunities. These opportunities could result in additional clinical trials or

development activities that would require a significant investment by the Company. Although Novoste has sufficient cash resources to fund its current commercial business, the development or acquisition of new technologies could require the Company to raise additional funds through bank facilities, debt or equity offerings or other sources of financing. Additional funding, if required, may not be available on satisfactory terms, or at all.

CERTAIN FACTORS THAT MAY IMPACT FUTURE OPERATIONS

WE DEPEND ON THE SUCCESSFUL DEVELOPMENT AND COMMERCIALIZATION OF THE BETA-CATH(TM) SYSTEM.

We began to commercialize the Beta-Cath(TM) System in the United States in November 2000 and our distribution system in Europe and certain Asian countries are still being developed. Substantially all of our revenue in the first nine months of 2001 has been from sales in the United States. We anticipate that for the foreseeable future we will be solely dependent on the continued 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 and on June 15, 2001, the Company received FDA approval for the 40-millimeter system; however, we may be unable to:

- 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, including coated stents, if and when approved for commercialization.

Commercialization of the Beta-Cath (TM) System in Europe is subject to certain additional risks. Physicians in Europe are generally less receptive to and slower to adopt new medical devices and technologies than physicians in the United States due to various factors, including the influence of national health care policies and reimbursement strategies of health care payers. We may never achieve significant revenue from sales in Europe or ever achieve or sustain profitability in our European operations. Our sales in selected European countries and several other countries aggregated approximately $1.8 million in 1999, approximately $4.2 million in 2000 and approximately $2.1 million for the first nine months of 2001.

WE HAVE LIMITED OPERATING HISTORY; WE HAVE A HISTORY OF LOSSES AND MAY NOT BE ABLE TO SUSTAIN THE PROFITABILITY WE ACHIEVED IN THE THIRD QUARTER OF 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 significant experience in manufacturing, marketing or selling our products in quantities necessary for sustaining profitability.

At September 30, 2001, we had accumulated a deficit of approximately $124.1 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 had our first quarter of profitability in the third quarter of

2001. Nevertheless, We may never:

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

- sustain profitability.

WE MAY NOT BE ABLE TO OBTAIN ADDITIONAL REGULATORY APPROVALS TO EXPAND BETA-CATH (TM) SYSTEM PRODUCT OFFERINGS OR TO BE ABLE TO MARKET THE BETA-CASH(TM) SYSTEM TO TREAT A BROADER RANGE OF INDICATIONS FOR THE UNITED STATES.

United States Market Approvals

On November 3, 2000, we received marketing approval from the FDA for the 30mm Beta-Cath(TM) System. On September 18, 2001, we received marketing approval from the FDA for the 40mm Beta-Cath (TM) System. These approvals limit 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 or a 40-millimeter radiation source train. In order to market the Beth-Cath(TM) System with radiation source trains longer than 40-millimeters, we will likely be required to demonstrate to the FDA that a 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, for example, to 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 a 60-millimeter radiation source train or modifications to the catheter or (2) 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 or application supplement covering the product design enhancement(s) or the broader range of indications for the device. In August 2001, we filed an application with the FDA for a pre-market approval supplement to use a 3.5 French catheter, or a smaller diameter, in the treatment of in-stent restenosis. The failure to obtain regulatory approval of this supplement in a timely manner could adversely affect Novoste's business.

The process of obtaining a pre-market approval and other required regulatory approvals can be expensive, uncertain and lengthy, and we may be unsuccessful in obtaining additional approvals to market the Beta-Cath (TM) System. 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 trails 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.

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. In August of 2001 we qualified to apply CE marking to the Beta-Cath(TM) 3.5F System. 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. On August 4, 2000, 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, in addition, 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.

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

Competition in the medical device industry, and specifically the markets for cardiovascular devices, is intense and characterized by extensive research and development efforts and rapidly advancing technology.

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 the 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 pre-marketing approval of its beta radiation device. Johnson & Johnson, and if it receives FDA approval, Guidant, 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 that does Novoste. We may not be able to compete effectively against Johnson & Johnson or Guidant.

Many of these same companies and others are researching coatings and treatments to coronary stents that could reduce restonsis and possibly be more acceptable to a medical community already experienced at using stents. Results from recent double blinded non-US clinical trials were reported as eliminating restenosis. Additional Clinical trials will need to be completed in order to confirm these results. If those trials are successful and completed in the time frames contemplated by the companies developing coated stents, coated stents, if approved for sale, could have a material adverse affect on Novoste's business as early as 2003 and could render vascular brachytherapy generall or the Beta-Cath (TM) System in particular noncompetitive. At least one competitor, Johnson & Johnson could receive FDA approval as early as late 2002 or early 2003.

Many of our competitors and potential competitors have substantially greater capital resources that 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 marketing, distribution, sales and servicing.

DEPENDENCE ON KEY PERSONNEL

Our business and future operating results depend in significant part upon the continued contributions of our key technical personnel and senior management, many of whom would be difficult to replace. Our business and future operating results also depend in significant part upon our ability to attract and retain qualified management, manufacturing, technical, marketing, sales and support personnel for our operations. Competition for such personnel is intense and we may not succeed in attracting or retaining such personnel. The loss of key employees, the failure of any key employee to perform adequately or our inability to attract and retain skilled employees, as needed, could materially adversely affect our business, financial condition and results of operations.

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 nine month period ended September 30, 2001, the closing price of our common stock ranged from a high of $39.50 per share to a low of $5.47 per share and ended that period at $5.93 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 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.

Item 3. Quantitative And Qualitative Disclosures About Market Risk

Interest Rate Risk

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

are intended to limit market risk by restricting the Company's investments to high credit quality securities with relatively short-term maturities.

At September 30, 2001, the Company had $14.3 million in cash equivalents with a weighted average interest rate of 3.30% and $22.1 million in available for sale investments with a weighted average interest rate of 3.40%. At September 30, 2000 the Company had $49.2 million in cash equivalents with a weighted average interest rate of 6.47% and $21.7 million in available for sale investments with a weighted average interest rate of 6.72%. All investments mature, by policy, in one year or less.

PART II. OTHER INFORMATION

Item 5. Other Information

The registrant's Chief Executive Officer is the only executive officer who has an employment agreement with the registrant. In September 2001, the registrant entered into change of control agreements with nine of the other executive officers. Each agreement provides that, following a Change in Control of the registrant, if the executive officer is terminated by registrant without Cause or leaves for Good Reason, then he or she will be entitled to a lump sum cash payment of two times his or her average annual compensation and any non-competition arrangement between the executive officer and registrant will terminate effective on the date of the Change in Control. The form of agreement is attached hereto as Exhibit 10.31 and incorporated herein by reference thereto.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

10.30 Loan and Security Agreement dated August 1, 2001 between Silicon Valley Bank and Novoste Corporation.
10.31 Negative Pledge Agreement dated August 1, 2001 between Silicon Valley Bank and Novoste Corporation.
10.32 Form of change of control agreement executed between Novoste Corporation and executive officers.

(b) Report on Form 8-K

The Company filed a Form 8-K on October 3, 2001 stating that a letter, dated September 25, 2001 had been mailed from the Registrant to the shareholders of the registrant. The purpose of the letter was to update the shareholders on second quarter, 2001 financial results and to address issues raised by the release of coated stent clinical trial results, a competitive technology.

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

November 13, 2001	/s/ Edwin B. Cordell, Jr.
Date	Edwin B. Cordell, Jr. Vice President - Finance, Chief Financial Officer (Principal Financial & Accounting Officer)