NOVOSTE CORP /FL/
Form 10-Q
August 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 June 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 August 1, 2001 there were 16,203,807 shares of the Registrant's Common Stock outstanding.

NOVOSTE CORPORATION

FORM 10-Q

INDEX

NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEETS

	June 30, 2001	Decemb
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 7,792,055	$
Short-term investments	28,845,851	
Accounts receivable, net of allowance of $599,244 at June 30, 2001 and $311,310 at December 31, 2000	13,270,313	

Inventories	2,391,803	
Prepaid expenses and other current assets	802,243	
Total current assets	53,102,265	
Property and equipment, net	8,895,904	
Radiation and transfer devices, net	8,805,691	
Other assets	1,309,708	
Total assets	$ 72,113,568	$
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,910,741	$
Accrued expenses	7,895,137	
Unearned revenue	3,069,427	
Capital lease obligations	123,807	
Total current liabilities	13,999,112	
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; 16,184,184 and 16,094,635 shares issued, respectively	161,842	
Additional paid-in-capital	186,517,178	1
Other accumulated comprehensive loss	(1,336,726)	
Accumulated deficit	(126,199,861)	(1
	59,142,433	
Less treasury stock, 5,780 shares of common stock at cost	(23,840)	
Unearned compensation	(1,479,289)	
Total shareholders' equity	57,639,304	
Total liabilities and shareholders' equity	$ 72,113,568	$

See accompanying notes.

NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

Three months ended June 30, Six mo

	2001	2000	2001
Net Sales	$17,290,707	$ 1,197,647	$ 26,581,3
Cost of Sales	5,725,840	770,013	9,470,3
Gross Margin	11,564,867	427,634	17,110,9
Operating expenses			
Research and Development	3,724,430	4,250,381	7,320,5
Sales and Marketing	9,149,095	2,987,702	16,435,3
General and Administrative	2,576,296	1,367,654	4,486,9
Total operating expenses	15,449,820	8,605,737	28,242,8
Loss from operations	(3,884,953)	(8,178,103)	(11,131,9
Interest income	606,169	1,053,899	1,247,8
Interest expense	(17,822)	(4,929)	(41,1
	588,347	1,048,970	1,206,7
Net loss	$(3,296,606)	$(7,129,133)	$ (9,925,1
Net loss per share Basic & Diluted	$ (0.20)	$ (0.45)	$ (0.
Weighted average shares outstanding	16,131,974	15,865,441	16,104,8

See accompanying notes.

NOVOSTE CORPORATION
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the six months ended Jun	
	2001	200
Cash flows from operating activities:		
Net loss	$ (9,925,174)	$(14,328
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	1,145,248	626
Issuance of stock for services or compensation	1,076,614	212
Amortization of deferred compensation	(241,069)	295
Amortization of radiation & transfer devices	1,440,662	
Provision for doubtful accounts	287,934	
Changes in assets and liabilities:		
Accounts receivable	(9,088,466)	(857

Inventory	(1,140,116)	1,717
Prepaid expenses	(319,860)	(144
Accounts payable	(514,509)	545
Accrued expenses	2,479,860	(427
Unearned revenue	2,488,610	46
Other assets	(1,610,317)	(4
Net cash used by operations	(13,920,582)	(12,320
Cash flow from investing activities:		
Maturity of short-term investments	1,809,585	10,223
Purchase of property and equipment	(2,658,484)	(1,742
Purchase of radiation and transfer devices	(4,765,405)	(2,451
Net cash (used) provided by investing activities	(5,614,304)	6,029
Cash flows from financing activities:		
Proceeds from issuance of common stock	929,850	54,264
Repayment of capital lease obligations	(115,307)	
Net cash provided by financing activities	814,543	54,264
Net (decrease) increase in cash and cash equivalents	(18,720,343)	47,973
Cash and equivalents at beginning of period	26,512,398	7,091
Cash and cash equivalents at end of period	$ 7,792,055	$ 55,064
SUPPLEMENTAL DISCLOSURE OF CASH FLOW		
Information:		
Cash paid for interest on capital lease obligation	$ (31,027)	$
Non-cash investing and financing activities:		
Assets acquired under capital lease	$ 105,000	$

See accompanying notes.

NOVOSTE CORPORATION
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
June 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

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 June 30, 2001 fair value approximated net book value for all short-term investments and all were considered available for sale and have been accounted for as such.

The effect of exchange rates on cash and cash equivalents was insignificant for the three and six month period ended June 30, 2001 and 2000.

NOTE 3. ACCOUNTS RECEIVABLE

Accounts receivable at June 30, 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 customers' 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 six month period ended June 30, 2001 amounted to approximately $12,000. There was no bad debt expense recorded for the six month period ended June 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:

	June 30, 2001	December 31, 2000
Raw Materials	$ 995,403	$ 777,819
Work in Process	483,487	218,958
Finished Goods	912,913	254,910
Total	$2,391,803	$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 June 30, 2001, equipment with a cost of approximately $6,568,000 before accumulated depreciation of approximately $1,441,000 was under operating leases. Approximately $3,678,000 of radiation and transfer devices were available for lease at June 30, 2001. At June 30, 2001, amounts receivable under these operating leases approximated $1,555,000 and are recorded in accounts receivable. Radiation and transfer devices are stated at cost and are comprised of the following:

	June 30, 2001	December 31, 2000
Radiation and Transfer Devices	$10,246,353	$5,612,763
Less: Accumulated Depreciation	1,440,662	131,815
Total	$ 8,805,691	$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 the Rest of World (Asia and South America)

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

	Six Months Ended June 30,			
	United States	Europe	Rest of World	Consolidated
2001	$24,028,800	$2,124,193	$428,343	$26,581,336
2000	125,000	1,674,770	243,923	2,043,693

At June 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 $5,696,000 and $2,819,000, respectively.

NOTE 8. SHAREHOLDERS' EQUITY

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

	Three Months	Six Months
Shareholders' Equity at beginning of period	$60,688,999	$67,042,119
Proceeds from exercise of 24,112 and 70,676 stock options ranging from $3.20 to $27.00 per share	274,703	885,366
Proceeds from issuance of stock under employee stock purchase plan, 18,873 shares on 4/2/01 at $14.93 per share	281,738	281,738
Deferred compensation relating to issuance of certain stock options	839,360	839,360
Amortization of unearned compensation	(419,076)	(241,069)
Comprehensive loss:		
Translation adjustment	(729,813)	(1,243,036)
Net loss	(3,296,607)	(9,925,174)
Total comprehensive loss	(4,026,420)	(11,168,210)
Shareholders' Equity at June 30, 2001	$57,639,304	$ 57,639,304

========== ==========

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 and 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 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 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 June 18, 2001, Novoste received US marketing approval for the 40-millimeter Beta-Cath(TM) System from the FDA.

Since our inception, through June 30, 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 significant experience in manufacturing, marketing or selling our products in quantities necessary for achieving profitability. At June 30, 2001, we had an accumulated deficit of approximately $126.2 million. We expect to continue to incur operating losses through at least 2001 as we continue to allocate resources to increasing our manufacturing operations, both internally and with outside vendors, continue to invest in expanding our sales and marketing efforts in support of United States market development and continue to 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. The Company also faces intense competition in the field of vascular brachytherapy with companies that have significantly greater

capital resources than Novoste. New technologies under development, including coated stents, 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 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 June 30, 2001 was $3,296,606 or ($.20) per share, as compared to $7,129,133 or ($.45) per share, for the three months ended June 30, 2000. Net loss for the six months ended June 30, 2001 was $9,925,174, or ($.62) per share, as compared to $14,328,075 or ($.95) per share, for the six months ended June 30, 2000. The decrease in net loss for the three and six months ended June 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 $17,290,707 and $26,581,336 were recognized in the three and six months ended June 30, 2001 as compared to net sales of $1,197,647 and $2,043,693 for the three and six months ended June 30, 2000. Net sales increased in both the three and six month periods due to sales of the Beta-Cath(TM) System in the U.S., following FDA pre-market approval of the system in November 2000. Net sales in the U.S. comprised approximately 90% of all net sales for the first six months of 2001. The significant growth in net sales in second quarter 2000 was primarily due to the rapid growth in the number of new hospitals leasing the Beta-Cath(TM) System in the U.S. as well as continued utilization in the existing sites. The Company added over 100 sites for the three months ended June 30, 2001 for a total of over 200 new sites for the year. The Company expects net sales to increase in the future as direct distribution is expanded in the U.S. The Company expects utilization to increase in the future with the recent FDA approval of the 40mm radiation source train and the radiation license guidance changes and anticipated reimbursement by third parties.

Cost of Sales. Cost of sales for the three months ended June 30, 2001 were $5,725,840 resulting in a gross margin of 66.9%, compared to cost of sales of $770,013 and gross margin of 35.7% for the same period of 2000. Cost of sales were $9,470,344 for the six months ended June 30, 2001 resulting in a gross margin of 64.4% as compared to cost of sales of $1,523,393 and a gross margin of 25.5% for the six months ended June 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. The Company expects cost of sales to increase as sales activities in the U.S. continue to grow. However, cost of sales are 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 12% to $3,724,430 for the three months ended June 30, 2001 from $4,250,381 for the three months ended June 30, 2000. For the six months ended June 30, 2001 research and development expenses decreased 16% to $7,320,567 from $8,725,921 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 as a result of anticipated new clinical trial activity.

Sales and Marketing Expenses. Sales and marketing expenses increased 206% to $9,149,095 for the three months ended June 30, 2001 from $2,987,702 for the three months ended June 30, 2000. For the six months ended June 30, 2001 sales and marketing expenses were $16,435,329 as compared to $5,357,206 for the six months ended June 30, 2000, an increase of 207%. 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 we launched the new Beta-Cath(TM) System in the U.S. The Company has built up a solid base of sales and marketing infrastructure to penetrate the market rapidly and expects sales and marketing expenses to increase in the future as direct distribution is expanded in the U.S., but expects a slower rate of increase as a percent of net sales. The Company expects that its recently modified sales commission program, which recognizes the completion of the initial product launch in the US and generally reduces the commission percentage on net sales beyond certain thresholds, will reduce commission expense as a percentage of net sales in the future.

General and Administrative Expenses. General and administrative expenses for the three and six months ended June 30, 2001 were $2,576,296 and $4,486,996 as compared to the three and six months ended June 30, 2000 of $1,367,654 and $2,415,155, and increase of 88% and 86%, respectively. The increase for the three and six month period was primarily the result of additional management personnel at higher salaries and information systems costs. Given the continued revenue growth, the Company expects general and administrative expenses to increase in the future in support of a higher level of operations, but at a slower rate as a percentage of net sales.

Interest Income. Net interest income decreased 44% to $588,347 for the three months ended June 30, 2001 from $1,048,970 for the three months ended June 30, 2000. Net interest income decreased 27% to $1,206,726 for the six months ended June 30, 2001 from $1,649,907 for the six months ended June 30, 2000. The decrease in interest income for the three and six months was primarily due to the decrease in average cash equivalent and short-term investment balances combined with falling interest rates.

LIQUIDITY AND CAPITAL RESOURCES

During the six months ended June 30, 2001 and 2000, the Company used cash to fund operations of $13.9 million and $12.3 million, respectively. The increase in cash used by operating activities of $1.6 million for 2001 over 2000 was primarily attributable to (i) $8.2 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) $2.8 million used to fund the purchase of increased levels of inventory, (iii) $.2 million used for prepaid expenses, (iv) $1.1 million used to pay accounts payable, and (v) $1.6 million increase in other assets, offset by (i) $4.4 million decrease in net loss, (ii) $2.6 million increase in earnings related to non-cash items, (iii) $2.9 million provided by accrued expenses, and (iv) $2.4 million increase in unearned revenue related to revenue recognized on radiation and transfer devices.

Net cash used by investing activities for the six months ended June 30, 2001 was $5.6 million and net cash provided by investing activities for the six months ended June 30, 2000 was $6.0 million. The $11.6 million increase in cash used in 2001 compared to 2000 was due to $8.4 million in short-term investments that matured, $.9 million to purchase additional property and equipment and $2.3 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 six months ended June 30, 2001 and 2000 provided net cash of $.8 million and $54.3 million, respectively. The change of $53.5 million resulted primarily from receiving net proceeds of $49.0 million in april 2000 for a private placement offering plus $5.3 million from the exercise of stock options during the six months ended June 30, 2000 and $.9 million from the exercise of stock options during the same period in 2001. In addition, the Company repaid $.1 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 $2 million for the quarter and $5.3 million for the six months ended June 30, 2000 from the exercise of stock options. In 2001, the Company received $.9 million from the exercise of stock options, all received during the second quarter of 2001.

At June 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 June 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 $273,944 and $17,024 for the six months ended June 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 $573,500 and $41,647 for the six months ended June 30, 2001 and 2000,

respectively, and have been expensed in Cost of Sales.

The Company's principal source of liquidity at June 30, 2001 consisted of cash, cash equivalents and short-term investments of $36.6 million. The Company did not have any credit lines available or outstanding borrowings at June 30, 2001.

The Company anticipates that its operating losses will continue through at least the third quarter of 2001 as it continues to expend additional resources to expand sales and marketing activities. 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 by early in 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.

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 half 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 18, 2001, the Company received FDA approval for the 40-millimeter system; 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.

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 six months of 2001.

WE HAVE LIMITED OPERATING HISTORY; WE HAVE A HISTORY OF LOSSES AND EXPECT FUTURE LOSSES THROUGH AT LEAST 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 achieving or sustaining profitability.

At June 30, 2001, we had accumulated a deficit of approximately $126.2 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 the third quarter of 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.

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-CATH(TM) SYSTEM TO TREAT A BROADER RANGE OF INDICATIONS FOR THE UNITED STATES

On November 3, 2000, we received marketing approval from the FDA for the 30mm Beta-Cath(TM) System. On June 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-millimerters, 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 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 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.

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 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.

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.

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.

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 by the State's nuclear regulatory agency 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). 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.

THE INDUSTRY IN WHICH WE PARTICIPATE IS SUBJECT TO RAPID TECHNOLOGICAL CHANGE AND INTENSE COMPETITION.

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. Guidant has publicly disclosed that it anticipates FDA pre-marketing approval of its beta radiation device in the third quarter of 2001. 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 than 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 restenosis and 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.

WE HAVE LIMITED MANUFACTURING EXPERIENCE AND MAY ENCOUNTER DIFFICULTIES IN SCALING-UP PRODUCTION.

To date, we have not yet successfully commercialized the Beta-Cath(TM) System in order to sustain profitability. 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 has required us to expand our manufacturing capabilities and to hire and train additional personnel. We do not have significant 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.

THE PRICE OF OUR STOCK IS SUBJECT TO VOLATILITY AND FLUCTUATIONS AND WILL DEPEND ON 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 six month period ended June 30, 2001, the closing price of our common stock ranged from a high of $39.50 per share to a low of $13.00 per share and ended that period at $25.50 per share.

WE DEPEND ON THE PROTECTION PROVIDED BY OUR ISSUED PATENT AND PENDING PATENT APPLICATIONS, WHICH MAY BE CHALLENGED.

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.

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 June 30, 2001, the Company had $7.8 million in cash equivalents with a weighted average interest rate of 3.80% and $28.8 million in available for sale investments with a weighted average interest rate of 4.13%. At June 30, 2000 the Company had $51.0 million in cash equivalents with a weighted average interest rate of 6.31% and $26.6 million in available for sale investments with a weighted average interest rate of 6.70%. All investments mature, by policy, in one year or less.

PART II. OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

(c) On June 14, 2001, the Company issued Dr. Charles Wilmer, a consultant, 1,000 restricted shares under its 2001 Stock Plan. The shares contain restrictions on transfer, which lapse over time or upon a change of control. The restrictions lapse on June 14, 2002, with respect to all of the shares. The shares were issued pursuant to an exemption from registration under the Securities Act of 1933 under Section 4(2) thereof. The shares were purchased for investment and the shares have been duly legended to reflect that they have not been registered under the Securities Act.

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

(a) The Company held its annual meeting of stockholders on June 14, 2001 and solicited votes by proxy in connection with such meeting.

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

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

	FOR	AGAINST	WITHHELD
William A. Hawkins	13,639,441	1,422,335	--
Donald Harrison, MD.	14,928,969	132,807	--

(ii) The shareholders approved the Company's 2001 Stock Plan with 6,803,434 votes in favor, 4,649,855 against and 36,195 abstained. There were 3,572,292 broker non-votes. Immediately following approval of the 2001 Stock Plan, the Board, at its meeting on June 14, 2001 approved amendments to the Plan to clarify that options must be granted at 100% of fair market value on the date of grant and to limit the number of shares that may be granted thereunder pursuant to awards that are not stock options to 10% of the shares reserved thereunder.

(iii) The shareholders approved an increase in the number of shares reserved for issuance under Novoste's Employee Stock Purchase Plan from 100,000 to 250,000 shares. Shareholders approved the plan amendment as follows: 11,267,686 in favor, 188,556 against and 33,242 abstained. There were 3,572,292 broker non-votes.

(iv) The ratification of the appointment of Ernst & Young LLP as independent auditors of the Company for the year ending December 31, 2001. The proposal received 14,863,798 votes in favor, 193,875 against and 4,103

abstained.

Item 5. Other Information

On June 14, 2001, Cheryl Johnson, the Company's Vice President of Business Development and Investor Relations resigned. Rob Walsh was elected by the Board as Vice President, Investor Relations to fill the vacancy created by Ms. Johnson's resignation, effective July 2, 2001.

On June 20, 2001, the Company entered into a new agreement with its primary supplier of radiation source trains, Bebig Gmbh. The new agreement, with a term of four years, supersedes all prior agreements and establishes minimum supply obligations for Bebig, prices of the product for the full term of the agreement and the costs of disposal for the radiation source trains.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

10.1	Copy of Novoste Corporation 2001 Stock Plan, as amended. Filed as Exhibit A to the Registrant's Proxy Statement for its 2000 Annual Meeting of Stockholders filed on April 30, 2001.
#10.29	Amendment to the Framework Agreement and Security Agreement (NOV 34) between Registrant and Bebig Isotopentechnik und Umweltdiagnostik GmbH

#Portions have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

(b) Reports on Form 8-K

The Company filed a Form 8-K on April 4, 2001,indicating that as stated in its Annual Report on Form 10-K for the year ended December 31, 2000, the Company had evaluated the impact of Staff Accounting Bulletin (SAB) 101,Revenue Recognition in Financial Statements, on its revenue recognition policies and concluded, based on its understanding of the SEC's ongoing interpretation of SAB 101, that the adoption of SAB 101 in 2000 did not require the Company to change its revenue recognition policies in its audited financial statements for the year ended December 31, 2000. The Registrant had previously disclosed and reported in its Form 10-Q for the quarter ended September 30, 2000, that the adoption of SAB 101 would require a change in its revenue recognition policies. The Company stated in the Form 8-K that it believed its adoption of SAB 101 would not have any material effect on the recognition of revenues during the year ending December 31, 2001.

SIGNATURES

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

NOVOSTE CORPORATION

August 14, 2001	/s/ Edwin B. Cordell, Jr.
Date	Edwin B. Cordell, Jr.

Vice President - Finance,
Chief Financial Officer
(Principal Financial & Accounting Officer)