NOVOSTE CORP /FL/
Form 10-Q
November 09, 2004
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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, 2004

¨ 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.)**
4350 International Blvd. Norcross, GA	**30093**
(Address of Principal Executive Offices)	**(Zip Code)**

(770) 717-0904

(Registrant s telephone, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such requirements for the past 90 days.

(Item 1) Yes x No ¨

(Item 2) Yes x No ¨

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes x No ¨

As of October 27, 2004 there were 16,334,705 shares of the registrant s common stock outstanding.

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FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

NOVOSTE CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except number of shares data)

	September 30, 2004	December 31, 2003
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,278	$ 33,177
Short-term investments	8,817	6,225
Accounts receivable, net of allowance of $160 and $442, respectively	3,806	5,206
Inventory, net	1,888	2,439
Prepaid expenses and other current assets	515	480
Total current assets	36,304	47,527
Property and equipment, net	4,650	6,997
Radiation and transfer devices, net	4,517	6,304
Other assets	2,366	579
Total assets	$ 47,837	$ 61,407
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 721	$ 1,492
Accrued expenses	5,836	6,483
Unearned revenue	1,743	188
Total current liabilities	8,300	8,163
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; 16,377,634 and 16,371,997 shares issued, respectively	164	164
Additional paid-in capital	187,894	187,880
Accumulated other comprehensive income	648	733
Accumulated deficit	(148,960)	(135,302)
Treasury stock, at cost, 42,929 shares	(172)	(172)
Unearned compensation	(37)	(59)
Total shareholders equity	39,537	53,244
Total liabilities and shareholders equity	$ 47,837	$ 61,407

See accompanying notes.

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NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per-share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net sales	$ 5,952	$ 13,531	$ 18,730	$ 51,845
Cost of sales	4,350	5,535	11,842	18,921
Impairment charge	938		938	
Gross margin	664	7,996	5,950	32,924
Operating expenses:				
Research and development	820	3,198	4,103	9,362
Sales and marketing	3,050	4,496	9,758	15,577
General and administrative	2,234	1,856	6,107	6,429
Total operating expenses	6,104	9,550	19,968	31,368
Income (loss) from operations	(5,440)	(1,554)	(14,018)	1,556
Interest income	104	40	265	223
Interest expense	(3)	(5)	(3)	(14)
Other income	66		98	5
Total other income	167	35	360	214
Net income (loss)	$ (5,273)	$ (1,519)	$ (13,658)	$ 1,770
Net income (loss) per share - Basic	$ (0.32)	$ (0.09)	$ (0.84)	$ 0.11
Weighted average shares outstanding - Basic	16,335	16,343	16,332	16,311
Net income (loss) per share - Diluted	$ (0.32)	$ (0.09)	$ (0.84)	$ 0.11
Weighted average shares outstanding - Diluted	16,335	16,343	16,332	16,743

See accompanying notes.

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NOVOSTE CORPORATION

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine Months Ended September 30,	
	2004	**2003**
Cash flows from operating activities:		
Net income (loss)	$ (13,658)	$ 1,770
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization of property, equipment and intangibles	2,489	2,629
Stock based compensation expense	20	86
Depreciation of radiation and transfer devices	3,041	6,984
Impairment charge	938	
Provision for doubtful accounts	(165)	(318)
Changes in assets and liabilities:		
Accounts receivable	1,556	1,054
Inventory	543	551
Prepaid expenses and other current assets	(36)	438
Other assets	161	835
Accounts payable	(765)	(1,209)
Accrued expenses	(643)	(3,469)
Unearned revenue	1,556	(2,271)
Net cash provided by (used in) operating activities	(4,963)	7,080
Cash flows from investing activities:		
Maturity/sale of short-term investments	7,622	14,556
Purchase of short-term investments	(10,214)	(9,271)
Purchase of property and equipment, net	(552)	(906)
Purchase of intangibles	(2,500)	
Purchase of radiation and transfer devices	(1,254)	(2,719)
Net cash provided by (used in) investing activities	(6,898)	1,660
Cash flows from financing activities:		
Proceeds from issuance of common stock	15	721
Purchase of treasury stock		(110)
Repayment of capital lease obligations		(169)
Net cash provided by financing activities	15	442
Effect of exchange rate changes on cash	(53)	192
Net increase (decrease) in cash and cash equivalents	(11,899)	9,374
Cash and cash equivalents at beginning of period	33,177	21,928
Cash and cash equivalents at end of period	$ 21,278	$ 31,302
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3	$ 14

See accompanying notes.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2004

NOTE 1. BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States 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 accounting principles generally accepted in the United States for complete financial statements. All normal and recurring adjustments considered necessary for a fair presentation of Novoste s financial results and condition 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, 2004. The accompanying unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2003, included in Novoste s 2003 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

The consolidated financial statements include the accounts of Novoste Corporation and its wholly owned subsidiaries incorporated in August 1998 in the Netherlands, in December 1998 in Belgium, in February 1999 in Germany, in January 2000 in France and in March 2002 a dedicated sales corporation incorporated in the state of Florida. Significant inter-company transactions and accounts have been eliminated.

Novoste sells its products with no right of return except in cases of product malfunction or shipping errors. On August 19, 2002, Novoste initiated a voluntary recall of the Beta-Rail 3.5F Delivery Catheter (the 3.5F catheter) inventory from its customers. The recall related to the discovery by Novoste of a small number of catheter tip separations in the 3.5F catheter product. An extensive evaluation and improvement program was initiated. A pre-market approval supplement was submitted to the U.S. Food and Drug Administration (FDA) on October 15, 2002, describing the improvements to the product and manufacturing processes and requesting approval for re-launch of the product. The FDA approved the re-launch on January 6, 2003.

In connection with the re-launch, Novoste exchanged 5.0F catheters for 3.5F catheters with a number of its customers. The exchange of these catheters was completed by September 2003 and all related reserves have been eliminated since that time. However, as of June 30, 2003, Novoste had recorded a reserve of approximately $400,000 to recognize the 5.0F catheters purchased prior to June 30, 2003, that were expected to be returned in the future for exchange to 3.5F catheters. The $400,000 in revenue was recognized in the quarter ended September 30, 2003.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2004

(continued)

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES

Novoste s significant accounting policies are included in the audited financial statements and notes thereto for the year ended December 31, 2003 included in Novoste s 2003 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Stock Options

Novoste accounts for grants of stock options and restricted stock under the recognition and measurement principles of Accounting Principles Board Option (APB) No. 25, *Accounting for Stock Issued to Employees* and related interpretations. The following table illustrates the effect on net income (loss) and earnings (loss) per share if Novoste had applied the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* as amended by SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure* (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss), as reported	$ (5,273)	$ (1,519)	$ (13,658)	$ 1,770
Add: Total stock-based employee compensation expense included in net income (loss)	3	15	20	87
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(651)	(826)	(1,735)	(3,106)
Pro forma net loss	$ (5,921)	$ (2,330)	$ (15,373)	$ (1,249)
Earnings (loss) per share:				
Basic-as reported	$ (0.32)	$ (0.09)	$ (0.84)	$ 0.11
Basic-pro forma	$ (0.36)	$ (0.14)	$ (0.94)	$ (0.08)
Diluted-as reported	$ (0.32)	$ (0.09)	$ (0.84)	$ 0.11
Diluted-pro forma	$ (0.36)	$ (0.14)	$ (0.94)	$ (0.08)

Asset Impairment

Novoste evaluates the carrying value of long-lived assets in accordance with the provisions of SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144) whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of assets to be held and used is determined based on the carrying value of an asset exceeding the future undiscounted net cash flow expected to be generated by the asset. If an asset is not recoverable, impairment is measured by the excess of the discounted future cash flows over the carrying value of the asset (see also Note 14 to the unaudited consolidated financial statements).

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2004

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NOTE 3. CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash equivalents are comprised of certain highly liquid investments with maturities of less than three months. In addition to cash equivalents, Novoste has investments in commercial paper and other securities that are classified as short-term. All securities are considered as available-for-sale and reported at fair value, with the unrealized gains and losses reported as a component of Other Comprehensive Income (Loss) on the consolidated statements of shareholders equity. The amortized cost of debt securities in this category, if significant, is adjusted for amortization and included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, of which there were none, would be included in interest income. Realized gains and losses are included in interest income and are determined on a specific identification basis. Interest and dividends on securities classified as available-for-sale are included in interest income.

NOTE 4. ACCOUNTS RECEIVABLE

Accounts receivable at September 30, 2004 and December 31, 2003 include receivables due from product sales and amounts due under lease and maintenance or service agreements with hospitals relating to radiation and transfer devices (see Note 7 to the unaudited consolidated financial statements). The carrying amounts reported in the consolidated balance sheets for accounts receivable approximate their fair value. Management records estimates of expected credit losses based on periodic credit evaluations of its customers financial condition.

Accounts receivables are comprised of the following (in thousands):

	September 30, 2004	December 31, 2003
Accounts receivable, gross	$ 3,966	$ 5,648
Less: Provision for doubtful accounts	(160)	(442)
Accounts receivable, net	$ 3,806	$ 5,206

There were no significant concentrations of credit risk at September 30, 2004.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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NOTE 5. INVENTORIES

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

	September 30, 2004	December 31, 2003
Raw materials	$ 2,102	$ 2,442
Work in process	256	124
Finished goods	866	1,115
Inventory, gross	3,224	3,681
Less: Inventory reserve	(1,336)	(1,242)
Inventory, net	$ 1,888	$ 2,439

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment are comprised of the following (in thousands):

	September 30, 2004	December 31, 2003
Furniture and fixtures	$ 1,056	$ 1,211
Office equipment	2,666	4,142
Laboratory equipment	801	991
Leasehold improvements	977	2,208
Production equipment	6,831	8,205
Property and equipment, gross	12,331	16,757
Less: Accumulated depreciation and amortization	(7,681)	(9,760)
Property and equipment, net	$ 4,650	$ 6,997

During the third quarter of 2004, Novoste recorded an impairment charge of $938,000 to reflect the reduced carrying value of production equipment (see Note 14 to the unaudited consolidated financial statements).

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2004

(continued)

NOTE 7. RADIATION AND TRANSFER DEVICES

Novoste retains ownership of the radiation source trains (RSTs) and transfer devices (TDs). Depreciation of the costs of these assets is taken over the estimated economic life using the straight-line method and is recorded in cost of sales. Depreciation begins at the time the Beta-Cath System is placed into service. Novoste classifies the annual agreements with Novoste s customers to license the use of radiation and transfer devices as operating leases. Income is recognized ratably over the length of the lease. At September 30, 2004, unearned revenue under these leases approximated $1,743,000, compared to $188,000 at December 31, 2003.

Radiation and transfer devices subject to operating leases, stated at cost, less accumulated depreciation, are comprised of the following (in thousands):

	September 30, 2004	December 31, 2003
Radiation and transfer devices, gross	$ 18,713	$ 25,554
Less: Accumulated depreciation	(14,196)	(19,250)
Radiation and transfer devices, net	$ 4,517	$ 6,304

In June 2002, Novoste decided to phase out the 5.0F diameter catheter systems, resulting in an impairment charge of $5,065,000 and other related charges of $1,835,000 (see Note 14 to unaudited consolidated financial statements) to adjust the carrying value of these assets to their fair value. The remaining fair value was being amortized on a straight-line basis over the remaining useful life, then estimated to end March 31, 2003.

In August 2002, Novoste initiated a voluntary recall of 3.5F diameter catheters. To meet patient needs, the 5.0F catheter system was reinstalled in sites where the 3.5F catheter system had previously supplanted the 5.0F catheter system. Notwithstanding its return to widespread active use, the 5.0F catheter system was still expected to be replaced by a redesigned 3.5F catheter system early in 2003. The new design for the 3.5F catheter system was submitted to the FDA on October 15, 2002 and was approved by the FDA for re-launch on January 6, 2003.

At December 31, 2002, approximately $1,650,000 of unamortized costs for the 5.0F catheter assets remained. During the first quarter of 2003, despite the re-launch of the newly designed 3.5F catheter system in January, it became apparent that the 5.0F assets would be utilized beyond the previously estimated termination date, and in fact, remained in active use through December 31, 2003. Factors leading to an extended life included: (a) the time required to convert customers to 3.5F catheter systems following the recall, (b) the time required to complete training on

the new 3.5F catheter replacement systems, and (c) allocations of 3.5F catheter systems to customer sites based on availability, customer preference and volume potential. Accordingly, the remaining value of the 5.0F catheter assets was amortized through December 31, 2003, rather than through March 31, 2003, as previously estimated. The result of this change in the estimated useful life increased amortization expense by $413,000 for the second, third and fourth quarters in 2003. The expense impact of this change in estimate of useful lives of the 5.0F catheter in the nine months ended September 30, 2004 and 2003 was $0 and $411,000, respectively, or $0.02 per share for the nine months ended September 30, 2003.

During the third quarter of 2004, approximately 1,400 of the 5.0F transfer devices, with an acquired cost of $8,512,000, were decommissioned because they had no foreseeable use. These assets were fully depreciated, thus, there was no effect on the income statement for the three and nine months ended September 30, 2004.

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NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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NOTE 8. OTHER ASSETS

Other assets consist mainly of license agreements and other intangibles. On April 22, 2004, Novoste signed an asset purchase agreement with Guidant Corporation (Guidant) pursuant to which Novoste would acquire information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant in the United States and Canada. Under the terms of the agreement, during a six-month transition period beginning on April 22, 2004, Guidant and Novoste would cooperate jointly to transition the Guidant customers to Novoste products for any customer that wishes to continue vascular brachytherapy. Guidant agreed to discontinue its vascular brachytherapy business in the United States and Canada over the six-month period. Additionally, Guidant has agreed to not compete in the vascular brachytherapy market in the United States and Canada for a period of five years. Novoste paid the sum of $2,500,000 to Guidant at the signing of the transaction and has agreed to pay Guidant an additional 5% on net sales to customers on the Guidant customer list that transition to Novoste s products for a period of six months after April 22, 2004. After this six-month transition period, Novoste will pay an additional 5% on all U.S. and Canadian net sales of Novoste vascular brachytherapy products up to a maximum of $4,000,000. The initial payment is being amortized over twenty-four months. Amortization expense was $313,000 and $521,000 for the three and nine months ended September 30, 2004, respectively.

NOTE 9. ACCRUED EXPENSES

Significant items of accrued expenses are as follows (in thousands):

	September 30, 2004	December 31, 2003
Salaries, wages and benefits	$ 2,584	$ 2,353
Accrued supplier and decommission cost	1,299	1,598
Due to customers	220	310
Operating expenses & royalties	515	643
Clinical trials	238	783
Professional fees	849	584
Sales and use taxes	131	212
	$ 5,836	$ 6,483

NOTE 10. LINE OF CREDIT

Since August 2001, Novoste has had a relationship with a financial institution (lender). On May 27, 2004, Novoste replaced previous borrowing arrangements with a one-year agreement, which provides a $5,000,000 revolving line of credit and availability of letters of credit. The lender will issue letters of credit for Novoste s account subject to certain limitations; and all such letters of credit may not exceed $2,000,000 in the aggregate.

Under the revolving line of credit, Novoste may borrow an amount not to exceed the borrowing base as defined in the loan agreement, which is principally based on domestic accounts receivable. Interest on outstanding balances is payable on the first of each month, calculated on the outstanding balance, and accrues at a rate of the lender s prime rate, which was 4.75% at September 30, 2004, plus 1%. To secure the payment and performance of all obligations when due, Novoste granted to the lender a first priority security interest in substantially all assets of Novoste.

At September 30, 2004 and December 31, 2003, Novoste had no outstanding borrowings. At September 30, 2004, $75,000 of the credit line was committed on letters of credit.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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NOTE 11. SEGMENT INFORMATION

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* requires the reporting segment information based on the information provided to Novoste s chief operating decision maker for purposes of making decisions about allocating resources and assessing performance. Novoste s business activities are represented by a single industry segment, the manufacture and distribution of medical devices. For management purposes, Novoste is segmented into two geographic areas: United States and the Rest of the World (Europe, Canada, Asia and South America).

The following is a summary of selected financial information by reportable segment as of, and for the nine months ended, September 30, 2004 and 2003 (in thousands):

Net sales

	United States	Rest of World	Consolidated
2004	$ 15,953	$ 2,777	$ 18,730
2003	48,235	3,610	51,845

Net income (loss)

	United States	Rest of World	Consolidated
2004	$ (13,178)	$ (480)	$ (13,658)
2003	1,920	(150)	1,770

Long-lived assets

	United States	Rest of World	Consolidated
2004	$ 10,662	$ 532	$ 11,194
2003	14,516	406	14,922

Total assets

	United States	Rest of World	Consolidated
2004	$ 45,320	$ 2,517	$ 47,837
2003	59,381	3,820	63,201

Novoste s total assets outside of the United States consist principally of cash and cash equivalents, accounts receivable and office equipment.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2004

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NOTE 12. EARNINGS PER SHARE

The following table sets forth the computation of basic and diluted earnings per share for the three and nine months ended September 30, 2004 and 2003 (in thousands, except per-share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Numerator:				
Net income (loss)	$ (5,273)	$ (1,519)	$ (13,658)	$ 1,770
Denominator:				
Weighted-average shares outstanding	16,335	16,343	16,332	16,311
Dilutive effect of stock options and unvested restricted stock				432
Weighted-average shares outstanding, assuming dilution	16,335	16,343	16,332	16,743
Net income (loss) per share:				
Basic	$ (0.32)	$ (0.09)	$ (0.84)	$ 0.11
Diluted	$ (0.32)	$ (0.09)	$ (0.84)	$ 0.11

The basic and diluted income or loss per share is computed based on the weighted average number of common shares outstanding. Weighted average shares outstanding, assuming dilution, includes the incremental shares that would be issued upon the assumed exercise of stock options. For the calculation of the three and nine months ended September 30, 2004, all stock options, representing approximately 3,354,000 shares of Novoste common stock, were excluded, as they would be anti-dilutive.

Of these, approximately 3,349,000 and 2,514,000 shares had an exercise price higher than the average price of Novoste s common stock for the three and nine months periods ended September 30, 2004, respectively.

For the three and nine months ended September 30, 2003, approximately 2,106,000 and 1,193,000 shares, respectively, were excluded, as their exercise price was higher than the average price of Novoste s common stock for these periods.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2004

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NOTE 13. SHAREHOLDERS EQUITY

Changes in shareholders equity consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Shareholders equity at beginning of period	$ 44,766	$ 57,018	$ 53,244	$ 52,765
Proceeds from exercise of stock options ranging from $3.20 to $6.65 per share		4	7	659
Proceeds from Employee Stock Purchase Plan, 3,637 shares at $2.2185 on 6/30/04 and 10,644 shares at $5.8225 on 6/30/03			8	62
Amortization of unearned compensation	5	28	40	111
Stock re-purchase of 25,600 shares in 2003		(110)		(110)
Revaluation of variable stock awards		(6)	(4)	(13)
Cancellation of options for services or compensation	(2)	(7)	(21)	(11)
Amortization of fair market value of stock options to non-employees			6	
Comprehensive income:				
Unrealized gain (loss) on available-for-sale securities	(1)	33	(15)	19
Translation adjustment	42	50	(70)	239
Net income (loss)	(5,273)	(1,519)	(13,658)	1,770
Total comprehensive income	(5,232)	(1,436)	(13,743)	2,028
Shareholders equity at end of period	$ 39,537	$ 55,491	$ 39,537	$ 55,491

NOTE 14. IMPAIRMENT CHARGES

In March 2002, Novoste began commercial distribution of a newer, smaller Beta-Cath System utilizing a 3.5F catheter. Original plans were to introduce the product slowly; however, the smaller diameter system allowed physicians to provide better and more comprehensive treatment to their patients, and demand for the new product exceeded expectations and the first-year goal of installed sites was achieved in less than four months. While the older 5.0F Beta-Cath Systems were still serviceable, during the second quarter of 2002, Novoste decided to concentrate marketing and development efforts on the 3.5F Beta-Cath System. Accordingly, Novoste evaluated the ongoing value of the 5.0F catheter systems that are equipped to be used with 30mm and 40mm radiation source trains. Based on this evaluation, Novoste determined that the transfer devices and radiation source trains, which were long-lived assets with a carrying amount of $8,600,000, were no longer recoverable and

wrote them down to their estimated fair value of $3,500,000, and accrued $1,800,000 for related expenses, resulting in an impairment and other related charges of $6,900,000 for the second quarter of 2002. Fair value was based on expected future net cash flows to be generated by the transfer devices and radiation source trains during their remaining service lives, discounted at the risk-free rate of interest. The remaining fair value was amortized ratably over the estimated useful life of these assets.

On August 19, 2002, Novoste announced the recall of all 3.5F diameter catheter products (see Note 1 to the unaudited consolidated financial statements). As a result, demand for the 5.0F diameter system increased significantly to service the patients needing vascular brachytherapy. This increased demand provided cash flow in excess of the carrying value. Following the re-launch of a redesigned 3.5F catheter system in January 2003, the 5.0F systems continued to be utilized at a declining rate. The revenue from the 5.0F systems continued to exceed carrying value and Novoste concluded that these assets would likely remain in active use through December 31, 2003. At December 31, 2003, no costs remained to be amortized for the 5.0F-impaired assets.

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NOVOSTE CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

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During the third quarter of 2004, Novoste suspended production of radiation source trains at AEA Technologies QSA GmbH (AEA). This suspension was due to the existence of radiation source train inventory levels that will be adequate to meet the needs of Novoste for the foreseeable future. This situation is due to (a) the reduction in the number of vascular brachytherapy sites and procedures as a result of the declining vascular brachytherapy market, and (b) fewer replacements of 3.5F radiation source trains than expected.

As a result of the suspension, Novoste undertook a study to assess the recoverability of carrying value of the AEA production facility in relationship to the expected discounted cash flows to be generated from revenues. Based on this study, Novoste concluded the value of the plant was no longer fully recoverable and recorded an impairment charge of $938,000 against the carrying value of $2,785,000 in property and equipment.

Effective September 30, 2004 Novoste concluded that the estimated useful commercial life of the production facility should be shortened from 60 months to 48 months, ending in September 2006 when the AEA Supply Agreement is up for renewal. The remaining value of the plant will be depreciated over this remaining useful life. At September 30, 2004, $1,847,000 remains to be depreciated.

NOTE 15. TERMINATION COSTS

In March 2004, Novoste announced a reduction in force, eliminating 84 positions, to align Novoste s staffing with current market conditions. Fifty-nine of the employees involved in the reduction terminated employment with Novoste during the three months ended March 31, 2004, and another 18 employees left during the three months ended June 30, 2004. The remaining 7 employees left during the third quarter ended September 30, 2004. The costs associated with terminated employees are included within operating expense in the unaudited consolidated statement of operations for the nine months ended September 30, 2004.

Thirty-seven employees located in the U.S. were terminated during the quarter ended March 31, 2003, and 50 more employees were terminated during the quarter ended September 30, 2003, to align Novoste s staffing with market conditions at the time. Termination costs of $761,000 were included in operating expense in the unaudited consolidated statement of operations for the nine months ended September 30, 2003.

Termination costs activity consisted of the following (in thousands):

	Three Months Ended September 30,	Nine Months Ended September 30,

	2004	2003	2004	2003
Accrued and paid during current period	$ 20	$ 504	$ 676	$ 700
Accrued but not paid during current period		61	10	61
Termination expense for the period	$ 20	$ 565	$ 686	$ 761

NOTE 16. RELATED PARTY TRANSACTIONS

On December 23, 2002, Novoste signed a Distribution Agreement with Orbus Medical Technologies, Inc., (Orbus) a manufacturer of cardiology products. Novoste s Chief Executive Officer, Mr. Alfred Novak, is also the Chairman of the Board of Directors of Orbus. During the first nine months of 2004, Novoste purchased $98,000 of product from Orbus at normal commercial prices. As of September 30, 2004, Novoste has prepaid $63,000 for future product purchases. During the nine months ended September 30, 2004, Novoste had net sales from this product line of $312,000, or 2% of total net revenues.

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

In this Form 10-Q, Novoste, the Company, we, us and our refer to Novoste Corporation and its subsidiaries. Beta-Cath® and the Novoste® logo are trademarks of Novoste.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The forward-looking statements in this Form 10-Q are made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended. Our operating results and financial condition have varied and may in the future vary significantly depending on a number of factors. Statements in this Form 10-Q which are not strictly historical statements, including, without limitation, statements regarding management s expectations for future growth and plans and objectives for future management and operations, future financial performance including losses and cash flows, domestic and international marketing and sales plans, product plans and performance, research and development plans, management s assessment of market factors, as well as statements regarding our strategy and plans, constitute forward-looking statements that involve risks and uncertainties. In some cases these forward-looking statements can be identified by the use of words such as may, will, should, expect, project, predict, potential or the negative of these words or comparable words. The factors lis Certain Factors Which May Affect Future Results in this Form 10-Q, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon our business, financial condition, and results of operations. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future global events or otherwise. Accordingly, you are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Novoste s discussion and analysis of its financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires that we adopt and follow certain accounting policies. Certain amounts presented in the financial statements have been determined based upon estimates and assumptions. Although we believe that our estimates and assumptions are reasonable, actual results will differ and could be material.

We have included below a discussion of the critical accounting policies that we believe are affected by our more significant judgments and estimates used in the preparation of our financial statements, how we apply such policies and how results differing from our estimates and assumptions would affect the amounts presented in our financial statements. Other accounting policies also have a significant effect on our financial statements, and some of these policies also require the use of estimates and assumptions.

Revenue Recognition

Revenue from the sale of products is recorded when an arrangement exists, delivery has occurred and services have been rendered, the seller s price is fixed and determinable and collectability is reasonably assured. Novoste earns revenue from sales of catheters, stents, and from service agreements for the use of radiation source trains and transfer devices included in the Beta-Cath System.

Novoste uses distributors in countries where the distributors experience and knowledge of local radiation and medical device regulatory issues is considered beneficial by Novoste s management. Under the distributor arrangements, there are generally no purchase commitments and no provisions for cancellation of purchases. Novoste or the distributor may cancel the distributor agreements at any time.

Revenue from sales of catheters directly to hospitals is recognized upon shipment after the hospital has received a Beta-Cath System and completed all licensing and other requirements to use the system. Novoste recognizes revenue from sales of catheters and stents at the time of shipment.

Novoste retains ownership of the radiation source trains and transfer devices and enters into a service agreement with its customers. Revenue recognition begins when an agreement has been executed, the system has been shipped, and all licensing and other requirements to use the system have been completed. The revenue is recognized ratably over the term of the agreement. Under the terms of the agreement signed with customers located in the United States, replacement and servicing of the radiation source train and transfer device is required at six-month intervals or twelve-month intervals, depending on the model of the device. This replacement and servicing cost is included in cost of sales as incurred. No other post-sale obligations exist.

Novoste sells its catheters with no right of return except in cases of product defect or shipping errors. In connection with the approval to re-launch the 3.5F catheter system on January 6, 2003, Novoste began exchanging with its customers 5.0F catheters for 3.5F catheters. A reserve was recorded against revenue for known returns and an estimate of unknown returns. The exchange of these catheters was completed by September 2003.

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Radiation and Transfer Devices and Amortization of Costs

Novoste has invested significant resources to acquire radiation source trains and transfer devices that make up the Beta-Cath System and offers multiple treatment options using either the standard length or the XL version of the 3.5F catheter, which can accommodate a 30mm, 40mm or 60mm radiation source train.

Novoste retains ownership of the radiation source trains and transfer devices that are used by customers. The costs to acquire, test and assemble these assets are recorded as incurred. Novoste has determined that based upon the manufacturer s data, the estimated economic life for radiation source trains is more than one year, and transfer devices is three years. Accordingly, Novoste classifies these assets as long-term assets. Depreciation of the costs of these assets is included in cost of sales and is recognized over their estimated economic lives using the straight-line method. Depreciation begins at the time the Beta-Cath System is placed into service. Valuation reserves are recorded for the balance of unamortized costs of transfer devices and radiation source trains that are on hand but not available for use by a customer.

During the second quarter of 2002, Novoste decided to concentrate marketing and development efforts on the 3.5F catheter system. Accordingly, Novoste evaluated the recoverability of the carrying value for 5.0F devices and other assets to determine if an impairment charge was necessary. Novoste performed this evaluation in accordance with the provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Based on this evaluation, Novoste determined that impairment and other related charges of $6,900,000 were warranted for the 5.0F assets for the second quarter of 2002 (see Notes 7 and 14 to unaudited consolidated financial statements). The 5.0F product line has completed its practical service life and, effective December 31, 2003, had no net book value.

Asset Impairment

Novoste evaluates the carrying value of long-lived assets in accordance with the provisions of SFAS 144 whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of assets to be held and used is determined based on the carrying value of an asset exceeding the future undiscounted net cash flow expected to be generated by the asset. If an asset is not recoverable, impairment is measured by the excess of the discounted future cash flows over the carrying value of the asset.

During the third quarter of 2004, Novoste suspended production of radiation source trains at AEA. This suspension was due to the existence of radiation source train inventory levels that will be adequate to meet the needs of Novoste for the foreseeable future. This situation is due to (a) the reduction in the number of vascular brachytherapy sites and procedures as a result of the declining vascular brachytherapy market, and (b) fewer replacements of 3.5F radiation source trains than expected.

As a result of the suspension, Novoste undertook a study to assess the recoverability of carrying value of the AEA production facility in relationship to the expected discounted cash flows to be generated from revenues. Based on this study, Novoste concluded the value of the plant was no longer fully recoverable and recorded an impairment charge of $938,000 against the carrying value of $2,785,000 in property and equipment.

Management will continue to evaluate its long-lived assets for impairment in accordance with SFAS No. 144.

Stock-Based Compensation

Novoste uses the intrinsic value method for valuing its awards of stock options and restricted stock and recording the related compensation expense, if any, in accordance with APB No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Novoste grants stock options generally for a fixed number of shares to employees, directors, consultants and independent contractors with an exercise price equal to the fair market value of the shares at the date of grant. Compensation expense is recognized for increases in the estimated fair value of common stock for any stock options with variable terms. No compensation expense is recognized for stock option grants to employees for which the terms are fixed and the exercise price is equal to the fair market value of the shares at the date of the grant.

Novoste accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation,* and as amended by SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, and Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

Any compensation expense related to grants that do not vest immediately is amortized over the vesting period of the stock options using the straight-line method as that methodology most closely approximates the way in which the option holder vests in those options.

Allowance for Doubtful Accounts

Novoste maintains allowances for doubtful accounts for the estimated losses resulting from the inability of our customers to make required payments. Most of our customers are hospitals located in the U.S.; however, some are distributors of our products in foreign countries or hospitals located in Europe. The amount recorded in the allowances is based primarily on management s evaluation of the financial condition of the customers. If the financial condition of any of the customers deteriorates, additional allowances may be required. Actual losses from uncollectible accounts are charged against the allowance when it is determined that the account cannot be collected.

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Inventories

Inventories are stated at the lower of cost or market value on a first-in, first-out (FIFO) basis. Provisions are recorded for excess or obsolete inventory equal to the cost of the inventory. Shelf-life expiration or replacement products in the marketplace may cause product obsolescence. If actual product demand and market conditions were less favorable than those projected by management, additional provisions might be required which would negatively impact operating profits. Novoste evaluates the adequacy of these provisions quarterly.

RESULTS OF OPERATIONS

Overview

The challenges of the first and second quarters of 2004 continued into the third quarter of 2004. We expect that revenues have and will continue to be impacted by the rapid acceptance of drug-eluting stents in the medical community and their success in reducing in-stent restenosis since their introduction into the U.S. market in April 2003. We expect that sales of our vascular brachytherapy products will continue to decline in 2004 as compared to 2003, resulting in a future reduction in our revenues. To address the revenue decline, on April 22, 2004, Novoste concluded an asset purchase agreement with Guidant Corporation, pursuant to which Novoste acquired information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant for the United States and Canada, as well as a five-year non-compete agreement. As a result, Novoste is now the sole provider of coronary brachytherapy products (see Note 8 to unaudited consolidated financial statements). As noted below, Novoste began an aggressive cost reduction program at the end of the first quarter of 2004 and initiated restructuring of operations in the United States in order to bring expenses in line with lower revenues. In addition, in June 2004, Novoste introduced a new transfer device that has a service cycle of 12 months. This new device, which replaces the earlier device that had a 6-month cycle, should reduce servicing costs. Also, during the second quarter of 2004, Novoste consolidated U.S. operations into a single building, with the expectation of significantly lowering fixed costs for facilities. In the third quarter of 2004, we saw the benefit of the Guidant transaction as approximately 80 customers were added or reinstated, billings for servicing transfer devices increased and our net rate of decline in catheter sales slowed. However, Novoste has sustained losses for the past 5 fiscal quarters. As of September 30, 2004, we had an accumulated deficit of $148,960,000. Our net loss was $5,273,000 in the third quarter of 2004. We anticipate that we will incur additional losses in future periods and that we will continue to have negative cash flow from operations for the foreseeable future. We also expect that these losses and negative cash flow will constitute a material use of our cash resources in 2005. We do not expect to achieve profitability in 2004 or 2005.

Due to the continuing challenges facing our vascular brachytherapy products business, we have been actively seeking new product opportunities, as well as a merger, business combination or other disposition of our business or assets. As part of our ongoing review of potential options, we retained an investment banking and strategic advisor, Asanté Partners LLC, in April 2004, to assist us in our efforts to identify and implement strategic and financial alternatives. We are continuing these efforts and, based on the outcome, will determine in the near term how best to respond to the challenges facing Novoste.

Net Sales and Gross Margin

Net sales and gross margin consisted of the following (in thousands):

	Three Months Ended September 30,	Nine Months Ended September 30,

	2004	2003	Increase (decrease)	2004	2003	Increase (decrease)
Net sales:						
United States	$ 5,163	$ 12,353	(58.2%)	$ 15,953	$ 48,235	(66.9%)
Rest of World	789	1,178	(33.0%)	2,777	3,610	(23.1%)
Total net sales	5,952	13,531	(56.0%)	18,730	51,845	(63.9%)
Cost of sales	4,350	5,535	(21.4%)	11,842	18,921	(37.4%)
Impairment charge	938			938		
Gross margin	$ 664	$ 7,996	(91.7%)	$ 5,950	$ 32,924	(81.9%)

Net sales decreased 56% in the third quarter and 64% in the first nine months of 2004 from the same periods in the prior year due to the rapid acceptance of drug-eluting stents. This decrease is due to the effectiveness of drug-coated stents in reducing in-stent restenosis during the early months following the implant of the stents, thus reducing the demand for Novoste s products. The completion of the Guidant transaction in the second quarter of 2004 had a positive effect on the third quarter, with revenue increasing 3% above the second quarter revenues due to the addition of approximately 80 former Guidant customers. Catheter revenue for the

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third quarter of 2004 declined at a slower rate, down only 2% from the second quarter of 2004. Revenues from lease and service agreements increased during the third quarter of 2004 due to marketing initiatives to recover costs for servicing the transfer devices. Such revenues increased 133% over the second quarter of 2004 and were 121% above the third quarter last year. Rest of World sales have significantly declined because of drug-eluting stents, but less than the U.S. market. These revenues declined 33% in the third quarter of 2004 and 23% for the first nine months of 2004 from the same periods last year.

In the quarter and nine months ended September 30, 2004, cost of sales declined approximately 21% and 37%, respectively, from the same periods of the prior year due to the significant reduction in revenues and the corresponding reduction of costs variable to sales. However, the reduction in total costs was not proportionate to the decline in revenues due to the relatively high fixed costs associated with the manufacturing and service operations. In the third quarter of 2004, we booked costs for future decommissioning of the AEA production facility, costs for disposal of radiation products, and minimum payments for the quarter to meet our contractual obligations under the AEA Supply Agreement. During the third quarter of 2004, Novoste recorded an impairment charge of $938,000 to reflect reduced carrying value of the AEA production facility for radiation source trains (see Note 14 to the unaudited consolidated financial statements).

The 92% and 82% decline in gross margin for the third quarter and the first nine months of 2004, respectively, was a result of the revenue decline coupled with relatively high fixed costs associated with manufacturing and service operations and the impairment charge on the production facility for radiation source trains.

We believe significant factors impacting cost of sales and gross margins going forward include the utilization of catheters at the sites using the Beta-Cath System and our ability to recover the servicing costs of transfer devices through the service agreements. We believe that the Guidant transaction will provide modest incremental revenue to cover some of the fixed costs, and that the consolidation of operations into a single building, completed in September 2004, will further reduce fixed costs. We also believe that depreciation of radiation devices, a component of cost of sales, will decline as the older devices complete their depreciable lives.

Operating Expenses

Operating expenses consisted of the following (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2004	2003	Increase (decrease)	2004	2003	Increase (decrease)
Operating expenses:						
Research and development	$ 820	$ 3,198	(74.4)%	$ 4,103	$ 9,362	(56.2)%
Sales and marketing	3,050	4,496	(32.2)%	9,758	15,577	(37.4)%
General and administrative	2,234	1,856	20.4%	6,107	6,429	(5.0)%
Total operating expenses	$ 6,104	$ 9,550	(36.1)%	$ 19,968	$ 31,368	(36.3)%

At the end of the first quarter of 2004, Novoste implemented a reduction in work force, eliminating 84 positions across all functions. This reduction is expected to lower annual operating costs by approximately $6,000,000. During the first quarter of 2004, approximately 59 of the individuals left Novoste, with the remaining individuals leaving during the second and third quarters. Approximately $686,000 of severance-related costs are included in the operating costs for the nine-months ended September 30, 2004.

The 74% decrease in research and development expenses for the third quarter and 56% decrease for the first nine months of 2004, compared to the same periods of the prior year, is primarily in the area of clinical trials, with the suspension of the MOBILE (More Beta Radiation In Lower Extremities) trial in mid-2003 and the BRAVO (Beta Radiation for treatment of Arterial-Venous graft Outflow) trials in the first quarter of 2004. In addition, some engineering projects underway in early 2003 have been completed and the engineers and staff involved with these projects have left Novoste. Current research and development efforts are focusing on the development of products that serve the coronary and cancer disease markets and that can utilize the marketing and distribution strengths of Novoste. Some research and development activities are being out-sourced to acquire specific skills that match the current product development needs.

The 32% and 37% decrease in sales and marketing expense for the third quarter and nine months ended September 30, 2004, respectively, is due to reduced sales and marketing personnel, and to significantly lower variable expenses related to lower revenues, principally commissions and travel expenses.

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The 20% increase during the third quarter of 2004, compared to the same period of the prior year, for general and administrative expenses is mainly due to consulting fees associated with the Sarbanes-Oxley Act compliance requirements, relocation expenses associated with consolidating U.S. operations into a single building, business consulting fees and incentives to retain key employees. The 5% decrease for the first nine months of 2004 is primarily due to the completion of significant computer systems projects that had been in process early in 2003 and ongoing cost reductions.

Other Income and Expenses

Other income for the third quarter of 2004 was $167,000 compared to $35,000 for the same period in the prior year. Other income for the first nine months of 2004 was $360,000 compared to $214,000 for the same period in the prior year. This net increase for the three and nine months ended September 30, 2004 arose primarily from slightly higher interest rates and receipt of funds in the third quarter of 2004 from the settlement of a lawsuit with affiliates of Durus Capital Management LLC (see Part II, Item 1 *Legal Proceedings* of our quarterly report on Form 10-Q for the quarter ended June 30, 2004).

Net Income (loss)

Net income (loss) consisted of the following (in thousands, except per share amounts):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2004	2003	Increase (decrease)	2004	2003	Increase (decrease)
Net income (loss)	$ (5,273)	$ (1,519)	$ (3,754)	$ (13,658)	$ 1,770	$ (15,428)
Net income (loss) per share - Basic	$ (0.32)	$ (0.09)	$ (0.23)	$ (0.84)	$ 0.11	$ (0.95)
Net income (loss) per share - Diluted	$ (0.32)	$ (0.09)	$ (0.23)	$ (0.84)	$ 0.11	$ (0.95)

The increase in net loss of $0.23 per share for the third quarter and the decline in net income of $0.95 per share for the nine months ended 2004, compared to the prior periods, was the result of significantly lower revenues, and the impact of the impairment charge for the AEA plant of $0.06 per share (see Note 14 to unaudited consolidated financial statements). The decline in operating income was partially offset by cost reduction initiatives during the first three quarters of 2004, but the decrease in revenues could not be fully offset due to relatively high fixed costs associated with sales, manufacturing and service operations. Net income in the third quarter of 2003 was positively affected by recognition of $400,000, or $0.02 per share of revenue previously deferred in the second quarter of 2003 for catheter exchanges completed in the third quarter of 2003, following the relaunch of the 3.5F catheter in January 2003.

LIQUIDITY AND CAPITAL RESOURCES

Operating

Net cash provided by (used in) operating activities consisted of the following (in thousands):

	Nine Months Ended September 30,	
	2004	**2003**
Cash flows from operating activities:		
Net income (loss)	$ (13,658)	$ 1,770
Depreciation and amortization of property, equipment and intangibles	2,489	2,629
Depreciation of radiation and transfer devices	3,041	6,984
Impairment charge	938	
Other non cash items	(145)	(232)
Net change in operating assets and liabilities	2,372	(4,071)
Net cash provided by (used in) operating activities	$ (4,963)	$ 7,080

Given the net loss in the first nine months of 2004, $4,963,000 of cash was used to fund the period s operating activities. This compares to $7,080,000 of cash generated in the same period of 2003. The changes in operating assets and liabilities are consistent with the decline in business volume. Depreciation of property and equipment has declined as a number of the capital assets installed when commercial production began in 2000 have reached, or are nearing, their depreciable lives. This decline is offset somewhat by

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amortization of the customer list obtained from Guidant during the second quarter of 2004. Depreciation on radiation and transfer devices is lower due to the completion of the commercial life of the older 5.0F systems, and the full amortization of these assets, as well as many of the older 3.5F systems completing their amortizable life. Included in the change in operating assets for the first nine months of 2004 was $1,556,000 generated from a reduction in receivables, compared to $1,054,000 for the same period of 2003 when receivables were collected faster than they were replaced by declining revenue. Offsetting funds generated by the collection of receivables were payments of accrued expenses and accounts payables of $1,408,000 and $4,678,000 for the nine-months ended September 30, 2004 and 2003, respectively. Unearned revenue related to the billing of service agreements (see Note 7 to the unaudited consolidated financial statements) increased by $1,556,000 in the third quarter of 2004, compared to a decline of $2,271,000 for the same period of prior year when agreements expired and were renewed at no cost to the customer due to competitive pressures.

Investing

Net cash provided by (used in) investing activities consisted of the following (in thousands):

	Nine Months Ended September 30,	
	2004	2003
Cash flows from investing activities:		
Maturity/sale of short-term investments	$ 7,622	$ 14,556
Purchase of short-term investments	(10,214)	(9,271)
Purchase of intangibles	(2,500)	
Capital expenditures, net	(1,806)	(3,625)
Net cash provided by (used in) investing activities	$ (6,898)	$ 1,660

Investments have been liquidated to fund the Guidant transaction and losses in operations. Less cash was used to purchase property and equipment in the nine months ended September 30, 2004 as compared to the same period of 2003, primarily due to the completion of in-house production facilities last year and only modest capital required to accommodate the move to a single building during the second quarter of 2004. Also, less cash was used to purchase radiation source trains and transfer devices compared to the same period in the prior year due to the declining vascular brachytherapy revenue. This decrease in purchases is due to the existence of radiation source train inventory levels that will be adequate to meet the needs of Novoste for the foreseeable future. In April 2004, Novoste purchased the vascular brachytherapy customer list from Guidant for $2,500,000, plus additional earned payouts, and is in the transition process of converting these accounts to the Novoste Beta-Cath System (see Note 8 to unaudited consolidated financial statements). It is expected that these new customers will be equipped with transfer devices and radiation source trains from current inventory.

Financing

During the quarter ended September 30, 2004, Novoste had no proceeds from the issuance of its common stock as a result of option exercises, compared to $4,000 in the third quarter of 2003 when employees exercised stock options. For the nine months ended September 30, 2004 and 2003, proceeds from stock option exercise were $7,000 and $659,000, respectively.

The Employee Stock Purchase Program allows employees to purchase Novoste stock at the ending dates of the second and fourth quarter of each year. For the June 30, 2004 purchase date, Novoste received $8,000, compared to $62,000 for the same date of preceding year.

In August 2003, Novoste announced the extension of the stock buy-back program that originally began in August 2002, but had been suspended due to the 3.5F catheter recall. The plan was extended in September 2003 and the extension authorized the purchases of up to $7,000,000. No shares were repurchased during the quarter ended September 30, 2004. As of September 30, 2004, 185,400 shares had been repurchased in earlier periods for $725,000.

In May 2004, Novoste replaced its working capital loan agreement and obtained a $5,000,000 revolving line of credit with the same financial institution (lender). The one-year agreement will expire on May 26, 2005. Novoste also has a letter of credit facility available under the revolving line of credit. The lender will issue or has issued letters of credit for Novoste s account subject to certain limitations. Under the credit facility, all such issued letters of credit may not exceed $2,000,000 in the aggregate. At September 30, 2004, Novoste had no outstanding borrowings, but had $75,000 in outstanding letters of credit. (see Note 10 to unaudited consolidated financial statements).

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Commitments

At September 30, 2004, Novoste had commitments to purchase $3,863,000 of products and services, primarily components for the Beta-Cath System. Of this amount, $1,333,000 has already been recorded as an accrued expense as of September 30, 2004. The decline in commitments compared to $4,683,000 at 2003 year-end and prior quarters in 2004 is due to lower business volume that requires less replacement of inventories and radiation devices.

On October 14, 1999, Novoste signed a development and manufacturing supply agreement with AEA for a source of radioactive supply and for the development of a smaller diameter radiation source. The agreement provided for the construction of a production line that was placed into service in October 2002. In addition, the agreement provides for joint ownership of all intellectual property arising from the development work and requires that AEA manufacture vascular brachytherapy sources only for Novoste. Unless notification to terminate is provided eighteen months prior to expiration, the agreement, which is effective until September 2006, automatically renews on a month-to-month basis in advance of the notification period. At the termination of this agreement, Novoste is obligated to reimburse AEA for the expense of decommissioning the production facility.

On June 20, 2001, Novoste amended its manufacturing and supply agreement with Bebig Isotopen-und Medizintechnik GmbH (Bebig), a German corporation, to manufacture and supply Novoste with radioactive sealed Strontium-90 seed trains. During each calendar year of the four-year contract, Novoste guarantees minimum annual payments to Bebig of varying amounts over the term of the agreement and provide up to $250,000 for decommission expense of the production facility. All product purchases are credited against the annual guaranteed payment. The term of this agreement will end on June 19, 2005.

Novoste 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 System (excluding consideration paid for the radioactive isotope), subject to a maximum aggregate payment of $5,000,000. Royalty fees paid to the physician were $53,000 and $126,000 for the three months ended September 30, 2004 and 2003, respectively, and $176,000 and $483,000 for the nine months ended September 30, 2004 and 2003, respectively. As of September 30, 2004, aggregate payments of $2,133,000 have been made under the license agreement and have been expensed as costs of sales.

On January 30, 1996, Novoste entered into a license agreement whereby Emory University assigned its claim to certain technology to Novoste for royalties based on net sales (as defined in the agreement) of products derived from such technology, subject to certain minimum royalties. After the first commercial sale of royalty bearing products by Novoste, minimum royalties were due to Emory University in the following amounts: year 2 after the first commercial sale $10,000; year 3 $15,000; year 4 $25,000; and years 5-10, $50,000 per year. The royalty agreement term is consistent with the life of the related patent and applies to assignments of the patent technology to a third party. Royalty fees paid to Emory University were $124,000 and $254,000 for the three months ended September 30, 2004 and 2003, respectively, and $383,000 and $983,000 for the nine months ended September 30, 2004 and 2003, respectively, and have been expensed as cost of sales.

On April 22, 2004, Novoste signed an asset purchase agreement with Guidant pursuant to which Novoste would acquire information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant in the United States and Canada. Novoste paid the sum of $2,500,000 to Guidant at the signing of the transaction and has agreed to pay 5% on its net sales of all vascular brachytherapy products in the U.S. and Canada, up to an additional payment of $4,000,000 (see Note 8 to unaudited consolidated financial statements). Under this agreement, Guidant has earned $72,000 and $85,000 in additional payments for the three months and nine months ended September 30, 2004, respectively.

Liquidity

Novoste s principal source of liquidity at September 30, 2004 consisted of cash, cash equivalents and short-term investments of $30,095,000, compared to $39,402,000 at December 31, 2003.

During the remainder of 2004, Novoste expects to allocate resources to continue product development and identify products complementary to applications for our Beta-Cath technology, identify products which could utilize our marketing and distribution skills, improve operating efficiencies for servicing transfer devices and transition the Guidant vascular brachytherapy business to the Novoste system. We expect that our existing cash reserves will be sufficient to fund any cash used by operations and meet our liquidity and capital spending needs at least through the end of 2004.

Novoste s future liquidity and capital requirements will depend upon numerous factors, including the risks discussed at Certain Factors Which May Affect Future Results below, and the following, among others: market demand for our products, especially with the acceptance of drug-eluting stents by our customers and the expected resulting decline in our revenues; the resources required to maintain a direct sales force in the United States and in Europe; the resources required to introduce enhancements to, and maintain the Beta-Cath System product lines; the resources Novoste devotes to the development, manufacture and marketing of its products; resources expended to license or acquire any new technologies; and the progress of Novoste s clinical research and product development programs. Novoste may in the future seek to raise additional funds through bank facilities, debt or equity offering or other sources of capital. Additional financing, if required, may not be available on satisfactory terms, or at all.

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CERTAIN FACTORS WHICH MAY AFFECT FUTURE RESULTS

In connection with the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, set forth below are cautionary statements identifying important factors that could cause actual events or results to differ materially from any forward-looking statements made by or on behalf of us, whether oral or written. We wish to ensure that any forward-looking statements are accompanied by meaningful cautionary statements in order to maximize to the fullest extent possible the protections of the safe harbor established in the Private Securities Litigation Reform Act of 1995. Accordingly, any such statements are qualified in their entirety by reference to, and are accompanied by, the following important factors that could cause actual events or results to differ materially from our forward-looking statements. For additional information regarding forward-looking statements, please read the Cautionary Note Regarding Forward-Looking Statements of this report.

We Are Dependent On The Success Of One Product, The Beta-Cath System.

We began to commercialize the Beta-Cath System in the United States in November 2000. Approximately 99% of our revenues in the third quarter of 2004 were from sales of this system. We anticipate that for the foreseeable future we will be solely dependent on the continued success of the Beta-Cath System; however, in the future we may be unable to manufacture the Beta-Cath System in commercial quantities at acceptable costs or to demonstrate that the Beta-Cath System is an attractive and cost-effective alternative or complement to other procedures, including coronary stents or drug-eluting stents. Because the Beta-Cath System is our sole near-term product focus, we could be required to cease operations if new technology rendered vascular brachytherapy non-competitive. Our failure to continue commercialization of the Beta-Cath System would have a material adverse effect on our business, financial condition and results of operations.

Wide Acceptance By The Medical Community of Drug-Eluting Stents Or Other New Technology Could Render Vascular Brachytherapy Generally Or The Beta-Cath System In Particular Noncompetitive or Obsolete And, In Turn, Could Cause Our Revenues To Decline.

Drug-eluting stents were introduced by Johnson & Johnson in April 2003 and by Boston Scientific in March 2004. The penetration of the drug-eluting stent products from these two companies is approximately 90% of the existing stent market, all but replacing bare metal stents. The drug-eluting stents have significantly less occurrence of in-stent restenosis than bare metal stents which reduces the available market for the Company s products. Furthermore, many physicians are using drug-eluting stents to treat in-stent restenosis instead of using vascular brachytherapy. Both Johnson & Johnson and Boston Scientific are conducting studies to determine the relative efficacy of drug-eluting stents to treat in-stent restenosis, compared to vascular brachytherapy. The results of these trials are not currently available, but if they are in favor the utilization of the drug-eluting stents, it could have a significant impact on the Company. Several other companies including Guidant Corporation and Medtronic have developed additional ways to incorporate coatings and drugs into stent platforms as they pursue new innovations in stents. With the rate of in-stent restenosis declining at a very rapid rate, the use of drug-eluting stents to treat in-stent restenosis, and new competitive technologies potentially reducing the in-stent restenosis market in which Novoste operates, we face significant challenges due to the declining revenues from sales of our vascular brachytherapy products.

We expect that sales of our vascular brachytherapy products will continue to decline, due to the rapid market acceptance of drug-eluting stents, resulting in a future reduction of our revenues.

We May Not Be Able To Enter Into An Acceptable Strategic Or Other Transaction In The Near Term.

As discussed above under Management s Discussion and Analysis of Financial Condition and Results of Operations Overview, we have engaged Asanté Partners LLC to assist us in the exploration of strategic alternatives. Based on the outcome of this process, we expect to determine in the near term how best to proceed to maximize stockholder value. However, we cannot predict whether, or when, a transaction will result from this process. In addition, we may need to seek additional funds to finance potential strategic transactions, but may not be able to obtain such funds on satisfactory terms, if at all. If a suitable transaction resolving Novoste s future on acceptable terms does not become available in the relatively near term, we will need to consider other alternatives, which could include the sale or shutdown of some or all of our operating assets and dissolution and liquidation. If Novoste were to liquidate, we cannot predict when we would be able to make a distribution to our stockholders; nor can we assure stockholders that the amount paid in liquidation would equal the price or prices at which our common stock has recently traded or may trade in the future. Any distributions in liquidation would be reduced by cash expenditures and by additional liabilities we may incur, and by the ultimate amounts paid in settlement of our liabilities.

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We May Be Unable To Compete Effectively Against Larger Better Capitalized Companies.

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

Our Patents And Proprietary Technology May Not Adequately Protect Our Proprietary Products.

Our policy is to protect our proprietary position by, among other methods, filing United States and foreign patent applications. On November 4, 1997, we were issued United States Patent No. 5,683,345, on May 4, 1999, we received United States Patent No. 5,899,882 (which is jointly owned by us and Emory University) and on January 11, 2000, we received United States Patent No. 6,013,020, all related to the Beta-Cath System. We also have several additional United States applications pending which cover other aspects of our Beta-Cath 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 adequate protection to us because competitors may be able to design functionally equivalent devices that do not infringe that patent. Our patents could also be reexamined, invalidated or circumvented. Furthermore, claims under our other pending applications may not be allowed, or if allowed, may not offer any protection or may be reexamined, invalidated or circumvented. In addition, competitors may have or may obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products in either the United States or international markets.

Compliance With Applicable Government Regulations: Ability To Successfully Complete Clinical Trials And Gain Market Approval For New Products

Our Beta-Cath System is regulated in the United States and foreign jurisdictions as a medical device. As such, we are subject to extensive regulation by the FDA, by other federal, state and local authorities and by foreign governments. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing approvals, a recommendation by the FDA that we not be permitted to enter into government contracts, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed.

The process of obtaining a pre-market approval and other required regulatory approvals can be expensive, uncertain and lengthy, and we may be unsuccessful in obtaining additional approvals to market new versions of the Beta-Cath System or new indications for the Beta-Cath System. The FDA may not act favorably or quickly on any of our submissions to the agency. We may encounter significant difficulties and costs in our efforts to obtain additional FDA approvals that could delay or preclude us from selling new products in the United States. Furthermore, the FDA may request additional data or require that we conduct further clinical studies, causing us to incur substantial cost and delay. In addition, the FDA may impose strict labeling requirements, onerous operator training requirements or other requirements as a condition of our market approval, any of which could limit our ability to market our systems. Labeling and marketing activities are subject to scrutiny by the FDA and,

in 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 the device, changes to manufacturing process, changes to the device package, changes in vendors that supply components, 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.

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The Hospitals With Which We Do Business May Be Delayed In Obtaining Or May Be Unable To Obtain The Licenses To Hold, Handle And Use Radiation That Are Required For Our Products.

Our business involves the import, export, manufacture, distribution, use and storage of Strontium-90 (Strontium/Yttrium), the beta-emitting radioisotope utilized in the Beta-Cath System s radiation source train. 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 have been required to amend their radiation licenses to include Strontium-90 prior to receiving and using our Beta-Cath System. Depending on the state in which the hospital is located, its license amendment will be processed by and its use of the isotope will be regulated by either the state, in states that have agreed to such arrangement, with the United States Nuclear Regulatory Commission or directly by the NRC. Obtaining any of the foregoing radiation-related approvals and licenses can be complicated and time consuming.

We May Be Unable To Obtain Foreign Approval To Market Our Products

In order for us to market the Beta-Cath System in foreign jurisdictions, we must obtain and retain required regulatory approvals and clearances and otherwise comply with extensive regulations regarding safety and manufacturing processes and quality. These regulations, including the requirements for approvals or clearance to market and the time required for regulatory review, vary from country to country, and in some instances within a country. We may not be able to obtain regulatory approvals in such countries or may be required to incur significant costs in obtaining or maintaining our foreign regulatory approvals. Delays in receipt of approvals to market our products, failure to receive these approvals or future loss of previously received approvals could have a material adverse effect on our business, financial condition, and results of operations.

Some Of Our Activities May Subject Us To Risks Under Federal And State Laws Prohibiting Kickbacks And False Or Fraudulent Claims

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal health care program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, laboratories and other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Since we may provide some coding and billing advice to purchasers of our products, and since we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

Product Liability Suits Against Us Could Result In Expensive And Time-Consuming Litigation, Payment Of Substantial Damages And Increases In Our Insurance Rates

The sale and use of our products could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time-consuming to defend, either of which could materially harm our business or financial condition. We cannot assure that our product liability insurance would protect our

assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

Our Quarterly Operating Results May Vary

Our operating results have fluctuated significantly in the past on a quarterly basis. We expect that our operating results may fluctuate significantly from quarter to quarter and we may experience profits or losses in the future depending on a number of factors, including the extent to which (a) our products are able to compete effectively against drug-eluting stents (b) the timing and level of reimbursement for our products by third-party payors vary, and (c) other factors occur, many of which are outside our control.

We Are Highly Dependent On Key Personnel

We are highly dependent on the principal members of our management and scientific staff. Loss of our key personnel would likely impede achievement of our strategic and operational objectives. To be successful, we must retain key employees and attract additional qualified employees.

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Our Lack Of Redundant Manufacturing Facilities and Suppliers Could Harm Our Business

We assemble all of our products at our facilities in Norcross, Georgia. The loss of these facilities would likely impede our manufacturing and sales efforts, which would materially and adversely affect our business and financial condition. Should this occur we would have to depend on outsourcing to produce our catheter products. Significant proportions of key components and processes relating to our products are purchased from a single source 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, our ability to produce the related product in a timely manner could be adversely affected. We attempt to mitigate these risks by working closely with key suppliers regarding our product needs and the maintenance of strategic inventory levels.

Issuance Of Preferred Stock May Adversely Affect The Rights Of Holders Of Common Stock Or Delay Or Prevent A Change Of Control Of The Company

In October 1996, our Board of Directors authorized 1,000,000 shares of Series A Participating Preferred Stock in connection with its adoption of a shareholder rights plan, under which we issued rights to purchase Series A Participating Preferred Stock to holders of the common stock. Upon certain triggering events, such rights become exercisable to purchase common stock (or, in the discretion of our board of directors, Series A Participating Preferred Stock) at a price substantially discounted from the then current market price of the common stock. Our shareholder rights plan could generally discourage a merger or tender offer involving our securities that is not approved by our board of directors by increasing the cost of effecting any such transaction and, accordingly, could have an adverse impact on shareholders who might want to vote in favor of such merger or participate in such tender offer.

Under our amended and restated articles of incorporation, our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences and privileges of those shares without any further vote or action by our shareholders. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any shares of preferred stock that may be issued in the future. While we have no present intention to authorize any additional series of preferred stock, such issuance, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could also have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock. The preferred stock may have other rights, including economic rights senior to the common stock, and, as a result, the issuance thereof could have a material adverse effect on the market value of the common stock.

Certain Provisions Of Our Charter, By-Laws And Florida Law May Delay Or Prevent A Change Of Control Of The Company

The amended and restated articles of incorporation provide for a classified Board of Directors, the existence of which could discourage attempts to acquire us. Additionally, in October 2002, our Board of Directors enacted two amendments to Novoste s by-laws intended to strengthen the provisions of the by-laws that protect Novoste and its shareholders from unfair or coercive takeover tactics. In general, the amendments set forth certain notice requirements for shareholders when calling a special meeting of Novoste s shareholders or submitting shareholder proposals (either a shareholder nomination of director or other business) at our annual meetings. In addition, the amended by-laws establish certain timing requirements for the setting of the record and meeting dates. We are also subject to the anti-takeover provisions of the Florida Business Corporation Act, the application of which may have the effect of delaying or preventing a merger, takeover or other change of control of Novoste and therefore could discourage attempts to acquire Novoste.

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Item 3. Quantitative And Qualitative Disclosures About Market Risk

Derivative Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments

Novoste does not participate in derivative financial instruments, other financial instruments for which the fair value disclosure would be required under SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, or derivative commodity instruments. All of Novoste s investments are in short-term, investment grade commercial paper, corporate bonds, certificates of deposit and U.S. Government and agency securities that are carried at fair value on our books.

Interest Rate Risk

Novoste s cash equivalents and short-term investments are subject to market risk, primarily interest rate and credit risk. Novoste s investments are managed by outside professional managers within investment guidelines set by Novoste. Such guidelines include security type, credit quality and maturity, and are intended to limit market risk by restricting Novoste s investments to high credit quality securities with relatively short-term maturities.

At September 30, 2004, Novoste had $21,278,000 in cash and cash equivalents with a weighted average interest rate of 1.49% and $8,817,000 in available-for-sale investments with a weighted average interest rate of 1.88%. With $21,278,000 in cash and cash equivalents having less than 90 days to maturity, and the balance of the portfolio investments that are in a stable investment rate environment, we believe the risk to principal associated with an increase in interest rates is minimal.

Foreign Currency Risk

International revenues from Novoste s foreign direct sales and distributor sales comprised 15% and 7% of total revenues for the nine-month periods ended September 30, 2004 and 2003, respectively. Sales to customers outside Europe and Canada are denominated in U.S. dollars, while European sales are denominated in Euros and British Pounds, and Canadian sales are in Canadian dollars. Novoste experienced an immaterial amount of transaction gains and losses for the nine months ended September 30, 2004. Novoste is also exposed to foreign exchange rate fluctuations as the financial results of its Dutch, Belgian, German and French subsidiaries are translated into U.S. dollars in consolidation. As exchange rates vary, these results, when translated, may vary from expectations and adversely impact overall expected profitability. The net effect of foreign exchange rate fluctuations on Novoste during the nine months ended September 30, 2004 was not material.

At September 30, 2004, Novoste s total future purchase commitments include $2,564,000 denominated in Euros. This amount was derived from converting such purchase obligations using a September 30, 2004 conversion rate of $1.2331 USD to 1 Euro. Some of these purchase obligations extend to 2006, and the actual settlement amount may be different from the amount presented, which is based on the conversion rate of September 30, 2004.

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Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures. As of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a 15(e) and 15d 15(e) of the Securities Exchange Act of 1934). Based on this evaluation, our Chief Executive Officer and Acting Chief Financial Officer have concluded that our disclosure controls and procedures are effective in timely notification to them of information we are required to disclose in our periodic Securities and Exchange Commission filings and in ensuring that this information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and regulations.

(b) Changes in Internal Control. During the period covered by this report, there have been no significant changes in our internal control over financial reporting that have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Novoste is subject to legal claims and assertions in the ordinary course of business. Except for the matters described in the annual report on Form 10-K for the year ended December 31, 2003 and in the quarterly reports on Form 10-Q for the quarters ended March 31 and June 30, 2004, filed with the Securities and Exchange Commission, we are not aware of any such claims or assertions that would have a material effect on Novoste.

On June 9, 2003, Calmedica, LLC, (Calmedica) a California limited liability corporation, filed suit against the Company and one of our customers, Rush-Presbyterian St. Luke s Medical Center (Rush) in the Northern District of Illinois, Eastern Division, alleging that Novoste and Rush infringe certain patents owned by Calmedica and that Novoste induces infringement of the method claims of the patents-in-suit by its customers, such as Rush.

The Company retained counsel and initiated a vigorous defense of the Calmedica suit. In response to Novoste s initial motions, the Court in Illinois severed the claims against the Company and Rush, stayed the proceedings against Rush and transferred the case against the Company to the U.S. District Court for the Northern District of Georgia.

The Company has been aware of the patents owned by Calmedica, which are the subject of this litigation, since early in the development of the Beta-Cath System. The patents were fully reviewed by both in-house employees and outside counsel and the Company believes that our products do not infringe the Calmedica patents. While the Company and its counsel believe that Calmedica is not likely to be successful on the merits, defense of the cases will require the expenditure of significant time and resources. Also, in the event Calmedica is successful in the suit, the amount of damages that could be awarded for infringement, or license or royalty fees that may be awarded could have a materially adverse effect on the Company s operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(c) In August 2002, Novoste initiated a stock buy-back program. Under the program, we have the authority to purchase shares up to $7,000,000. The program may be suspended at any time and from time to time without prior notice. The program was suspended in connection with the 3.5F catheter recall in August 2002 and reinstated in September 2003. No shares were purchased during the first nine months of 2004. As of September 30, 2004, 185,400 shares had been repurchased for $725,000.

Item 3. Defaults Upon Senior Securities

None.

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

None

Item 5. Other Information

None.

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Item 6. Exhibits Note: New Form 10-Q amendment

EXHIBIT NUMBER	DESCRIPTION
3.1	Amended and Restated Articles of Incorporation of Registrant, filed on May 28, 1996. (1)
3.2(a)	Copy of First Amendment to Amended and Restated Articles of Incorporation of Registrant filed with the Department of State of the State of Florida on November 1, 1996. (2)
3.3	Copy of Third Amended and Restated By-Laws of Registrant dated May 5, 2003. (3)
4.1	Form of Specimen Common Stock Certificate of Registrant. (4)
4.17(a)	Amended and Restated Rights Agreement, dated as of July 29, 1999, between Novoste Corporation and American Stock Transfer and Trust Company, which includes as Exhibit B thereto the Form of Right Certificate. (5)
4.17(b)	Amended and Restated Summary of Rights to Purchase Preferred Shares of Novoste Corporation. (5)
4.20	Registration Rights Agreement dated as of March 28, 2000 by and between Novoste Corporation and the investors listed on the signature pages thereto. (6)
31.1	Certification of Alfred J. Novak, Chief Executive Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Subhash C. Sarda, Acting Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Statements of Alfred J. Novak, Chief Executive Officer, and Subhash C. Sarda, Acting Chief Financial Officer, pursuant to 18 U.S.C. Section 1350.*

(1) Filed as same numbered Exhibit to the Registrant s Report on Form 10-K filed on March 11, 2004.
(2) Filed as same numbered Exhibit to the Registrant s Report on Form 8-A filed on November 5, 1996.
(3) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed on November 4, 2003.
(4) Filed as same numbered Exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-03374).
(5) Filed as same numbered Exhibit to the Registrant s Registration Statement on Form 8-A/A (File No. 000-20727).
(6) Filed as same numbered Exhibit to the Registrant s Report on Form 8-K filed April 6, 2000.
* Filed herewith

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SIGNATURES

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

NOVOSTE CORPORATION

/s/ SUBHASH C. SARDA

SUBHASH C. SARDA
Acting Chief Financial Officer Principal Financial and Accounting Officer

November 9, 2004

Date