NOVOSTE CORP /FL/
Form 10-K
April 01, 2002

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2001.

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934.

For the transition period _____ to _____ .
Commission File Number: 0-20727

NOVOSTE CORPORATION
(Exact name of registrant as specified in its charter)

Florida	59-2787476
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3890 Steve Reynolds Blvd., Norcross, GA (Address of principal executive offices)	30093 (Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.01 par value
(Title of Class)

Rights to Purchase Preferred Shares
(Title of Class)

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. Yes [X] No [_]

Indicate by check mark if disclosures of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to

the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [_]

As of March 1, 2002, there were 16,315,676 shares of Common Stock outstanding. The aggregate market value of voting stock held by non-affiliates of the Registrant was approximately $103,957,000 based upon the closing sales price of the Common Stock on February 28, 2002 on the Nasdaq National Market. Shares of Common Stock held by each officer, director, and holder of five percent or more of the Common Stock outstanding as of March 1, 2002 have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's Proxy Statement for its Annual Meeting of Stockholders, which the Registrant intends to file not later than 120 days following December 31, 2001, are incorporated by reference to Part III of this Form 10-K Report.

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PART I

ITEM 1. BUSINESS

In this Form 10-K, "Novoste," the "Company," "we," "us" and "our" refer to Novoste Corporation. Novoste(R), Beta-Cath/TM/, Corona(R) and the Novoste(R) logo are trademarks of the Company.

General

Novoste, a Florida Corporation, has developed the Beta-Cath/TM/ System, a hand-held device to deliver beta, or low penetration, radiation to the site of a treated blockage in a coronary artery to decrease the likelihood of restenosis. Restenosis, the renarrowing of a previously treated artery, is the major limitation of percutaneous coronary intervention or PTCA, a procedure used by interventional cardiologists to open blocked coronary arteries. Coronary stents, metal tubes or coils permanently deployed at a blockage in a coronary artery, were developed to reduce the incidence of restenosis, however restenosis still occurs in greater than 30% of the patients who receive stents. In August 1998, we qualified to apply CE marking to the Beta-Cath/TM/ System, a requirement to sell our device in most of Western Europe and commenced the active marketing of our device in Western Europe in January, 1999. On November 3, 2000, Novoste received U.S. marketing approval from the FDA for the Beta-Cath/TM/ System (30-millimeter source train) for use in patients suffering from "in-stent restenosis", a condition in which previously placed coronary stents become clogged with new tissue growth. Novoste received additional approvals from the FDA for The Beta-Cath(TM) System with a 40millimeter source train during 2001 and the 60-millimeter source train and smaller, 3.5 French catheter and source train in early 2002.

The Company has principal operations in the United States and sales and disribution in Western Europe and Rest of World (Canada, Asia and South America). The Company markets its products through a direct sales force in the United States and a combination of direct sales representatives and independent disributors in markets outside the United States. All revenues have been generated from the marketing of the Beta-Cath(TM) System and during 2001, 93% of net sales were generated in the United States. Information concerning revenues and long lived assets by geographic area for the past three years may be found in Item 14 under Notes To Consolidated Financial Statements, Note 11. Segment Information.

Industry Overview

Coronary Artery Disease. Coronary artery disease is the leading cause of death in the United States. More than 13 million people in the United States currently suffer from coronary artery disease, which is generally characterized by the progressive accumulation of plaque as a result of the deposit of cholesterol and other fatty materials on the walls of the arteries. The accumulation of plaque leads to a narrowing of the interior passage, or lumen, of the arteries, thereby reducing blood flow to the heart muscle. When blood flow to the heart muscle becomes insufficient, oxygen supply is restricted and a heart attack and death may result. Depending on the severity of the disease and other variables, patients will be treated either surgically with CABG or less invasively with a PTCA procedure.

Coronary Artery Bypass Graft Surgery. Coronary artery bypass graft surgery, or CABG, was introduced as a treatment for coronary artery disease in the 1950's. CABG is a highly invasive, open surgical procedure in which blood vessel grafts are used to bypass the site of a blocked artery, thereby restoring blood flow. CABG, still considered the most durable treatment for coronary artery disease, is generally the primary treatment for severe coronary artery disease involving multiple vessels. In addition, CABG is often a treatment of last resort for patients who have undergone other less invasive procedures like PTCA but require revascularization. However, CABG has significant limitations, including medical complications such as stroke, multiple organ dysfunction, inflammatory response, respiratory failure and post-operative bleeding, each of which may result in death. In addition, CABG is a very expensive procedure and requires a long recovery period. In the United

States, the average cost of undergoing CABG, including hospital stay, is approximately $45,000; and the average recuperation period following discharge from the hospital is at least four to six weeks. In 2001, approximately 400,000 CABG procedures were performed in the United States. Several new minimally invasive surgical techniques have been commercialized which attempt to lessen the cost and trauma of CABG procedures while maintaining efficacy.

PTCA. Since its introduction in the late 1970s, PTCA has emerged as the principal less invasive alternative to CABG. PTCA is a procedure performed in a cath lab by an interventional cardiologist. During PTCA, a guidewire is inserted into a blood vessel through a puncture in the leg (or arm, in some cases) and guided through the vasculature to a diseased site in the coronary artery. A balloon-tipped catheter is then guided over the wire to the deposit of plaque or lesion occluding the artery. Once the balloon is positioned across the lesion inside the vessel, the balloon is inflated and deflated several times. Frequently, successively larger balloons are inflated at the lesion site, requiring the use of multiple balloon catheters. The inflation of the balloon cracks or reshapes the plaque and the arterial wall, thereby expanding the arterial lumen and increasing blood flow. However, the inflation of the balloon typically results in injury to the arterial wall. In 2001, it is estimated that about 400,000 PTCA procedures were performed in the United States and approximately 600,000 procedures were performed outside the United States. The average cost of each PTCA procedure in the United States is approximately $20,000, or less than one-half of the average cost of CABG. The length of stay and recuperation period are substantially less than those required for CABG.

Though PTCA has grown rapidly as a highly effective, less invasive therapy to treat coronary artery disease, the principal limitation of PTCA is the high

rate of restenosis, the renarrowing of a treated artery, which often requires reintervention. Studies have indicated that, within six months after PTCA, between 30% and 50% of PTCA patients experience restenosis.

Pathology of Restenosis. Restenosis is typically defined as the renarrowing of a treated coronary artery within six months of a revascularization procedure such as PTCA to less than 50% of its normal size. Restenosis is a vascular response to the arterial trauma caused by PTCA. Due to multiple mechanisms controlling vascular repair, restenosis may occur within a short period after a revascularization procedure or may develop over the course of months or years.

Restenosis that occurs within a day of a revascularization procedure is usually attributed to elastic recoil (acute loss of diameter) of the artery. Restenosis also may result from hyperplasia, which is the excessive proliferation of cells at the treatment site, or from vascular remodeling of the arterial segment, which is a slow contraction of a vessel wall. Hyperplasia is a physiological response to injury, similar to scarring, which occurs in wound healing. Vascular remodeling is a contraction of the vessel caused by a thickening of the outside wall of the artery. In response to an arterial injury from revascularization, the body sets off a biochemical response to repair the injured site and protect it from further harm. This response will include a signal to adjacent cells of the arterial wall to multiply. Often this cell proliferation goes unchecked, resulting in a much thicker and inelastic arterial wall and in reduced blood flow. Hyperplasia and vascular remodeling are the primary causes of restenosis.

Coronary Stenting. Coronary stents are expandable, implantable metal devices permanently deployed at a lesion site. Stents maintain increased lumen diameter by mechanically supporting the diseased site in a coronary artery. Of all the non-surgical treatments seeking to improve upon PTCA, stents have been the most successful in improving the outcome immediately following the procedure and reducing the incidence of restenosis. In a typical stent procedure, the artery is pre-dilated at the lesion site with a balloon catheter, and the stent is delivered to the site of the lesion and deployed with the use of a second balloon catheter which expands the stent and firmly positions it in place. This positioning may be followed by a third expansion, using a high-pressure balloon to fully deploy and secure the stent. Once placed, stents exert radial force against the walls of the coronary artery to enable the artery to remain open and functional.

Studies have concluded that the rate of restenosis in patients receiving coronary stents following PTCA is approximately 30% lower than in patients treated only by PTCA. Since their commercial introduction in the United States in 1994, the use of stents has grown rapidly, and it is estimated that they were utilized in over 75% of the approximately 1.5 million PTCA procedures performed in 2001.

Despite their rapid adoption, stents have certain drawbacks. The use of stents increases the cost of a PTCA procedure, especially when, as is often the case, two or more stents are used. In addition, studies have shown that restenosis still occurs in approximately 30% to 40% of the patients who receive stents following PTCA. This is commonly referred to as "in-stent" restenosis. Studies have shown that patients with "in-stent" restenosis often experience recurrent restenosis and as a result are prone to multiple revascularization procedures. Stents are also permanent implants which may result in unforeseen, long-term adverse effects, and cannot be used in cases where the coronary arteries are too tortuous or too narrow. Further, stents appear to be effective in reducing the frequency of restenosis resulting from elastic recoil and

vascular remodeling, but they increase the degree of hyperplasia.

Studies conducted by Novoste and other companies using radiation to treat in-stent restenosis led to FDA approval and the subsequent introduction of vascular brachytherapy devices in 2000 and 2001. These devices have proven to reduce in-stent restenosis but because of the complexity of using radiation in the cath lab other companies have been researching coatings and treatments to coronary stents that could also reduce restenosis and would possibly be more acceptable to a medical community already experienced at using stents. Even though early trial results of drug coated stents have been reported as eliminating restenosis, the Company believes there will continue to be a market for vascular brachytherapy in the foreseeable future. Only one of the drug coated stents, Johnson & Johnson's, has continued development in its current configuration as other companies are seeking to test multiple drug coating in an effort to find the drug will reduce restenosis without creating additional damage to the artery. Additionally, Novoste believes that the early clinical data is not representative of the wide variety of patients that will be treated by a wide variety of physicians in unmonitored settings. Those patients who do restenos will still benefit from treatment with vascular brachytherapy. From an economic standpoint it also may not be practical or possible for most hospitals to use drug-coated stents on all their patients, since the price of new stents is projected to be about three times the price of traditional bare metal stents.

The Novoste Solution

The Beta-Cath/TM/ System has been shown to reduce the incidence of restenosis in patients who are being treated for blocked stents, or in-stent restenosis. The administration of localized beta radiation reduces restenosis rates by inhibiting hyperplasia and vascular remodeling. Radiation has been used therapeutically in medicine for more than 50 years in the treatment of proliferative cell disorders, such as cancer. Cancer therapy has primarily involved the use of gamma radiation, which is highly penetrating and may be hazardous unless handled and used with great care. By contrast, beta radiation is far less penetrating and easier to use and shield than gamma radiation while still delivering a sufficient dose to the treated coronary arteries. We view beta radiation as well-suited for intracoronary use following PTCA, where the objective is to treat the coronary artery with minimal exposure to adjacent tissues.

The Beta-Cath/TM/ System is designed to fit well with techniques currently used by interventional cardiologists in the cath lab. It is a hand-held device that hydraulically delivers beta radiation sources through a closed-end catheter to the area of the coronary artery injured by the immediately preceding PTCA procedure. To facilitate easy placement of the catheter, it is advanced over the same guidewire used in the PTCA procedure. After the administration of the prescribed radiation dose to a lesion site, which takes less than five minutes per lesion, the radiation sources are hydraulically returned to the hand-held transfer device. We reuse the radiation isotopes for eighteen months due to the long half-life of Strontium-90, the isotope used in Novoste device.

Our Business Strategy

Our objective is to maintain our leadership position in the vascular brachytherapy market and leverage our catheter technology expertise, our strong distribution network and our ability to execute development, clinical trials and market introduction of new technology. Elements of our strategy include:

- Maintaining our vascular brachytherapy market leadership position. We've enhanced the already successful system with a small-diameter catheter that was approved by the FDA in February 2002, and a 60mm radiation source train that was approved in March 2002. We anticipate these additional Beta-Cath(TM) System product offerings will enable interventional cardiologists greater ability to treat in-stent restenosis.

- Increasing revenue and improving earnings per share in 2002 through enhancements to the Beta-Cath(TM) System and the availability of reimbursement. We are also working to further improve manufacturing efficiencies and control costs.

- Filing for FDA approval of peripheral products in 2003. We hope to expand our radiation technology into larger markets--like treating femoral-popliteal (fem-pop) disease and arterial-venous (A-V) dialysis grafts--where drug-coated stents are not likely to be a competitive threat. We have already initiated our fem-pop trial, and are working towards starting the A-V graft trial very soon.

- Diversify our revenue from new products by 2004. We have in progress a number of development programs seeking to provide novel technologies and products that will enable new treatment opportunities for the most challenging diseases in cardiology and related markets. These programs are targeted at markets with significant market potential.

- Funding operating and product development activities internally. Based on our sales and profitability goals, we expect to generate substantial net income that can fund our development and acquisition efforts.

Beta-Cath/TM/ System Design and Advantages

The primary components of the Beta-Cath/TM/ System are:

Radiation Source Train. The beta radiation administered by the Beta-Cath/TM/ System emanates from a "train" of several miniature sealed sources containing Strontium-90 (Strontium/Yttrium), a beta-emitting radioisotope. We currently manufacture trains in 30mm, 40mm and 60mm lengths, with the longer length intended for use on longer lesions. The use of beta, rather than gamma, radiation is intended to make the Beta-Cath/TM/ System safer and easier to use in the cath lab environment. In addition, due to the long half-life (approximately 28 years) of Strontium-90, and because the source train will not come into contact with a patient's blood or tissue, the radiation sources are expected to be reused for up to eighteen months. Beta radiation from the Strontium-90 source is easily shielded from health care workers by the use of approximately one-half-inch-thick quartz in the transfer device.

Transfer Device. The transfer device is a multiple-use, hand-held instrument used to deliver, retrieve and then store the radiation sources when not in use. The transfer device:

- transfers the radiation sources to and from the delivery catheter via a proprietary hydraulic delivery system;

- contains a radiation source sensing system which is interlocked with a gating system to prevent the radiation sources from exiting the transfer device until the delivery catheter is locked in place and to prevent removal of the delivery catheter prior to the return of the radiation sources to the transfer device; and

- completely shields the beta radiation from health care workers when the radiation source train is housed inside it.

Delivery Catheter. The delivery catheter is a single-use, multi-lumen catheter that provides a pathway for the radiation sources to be rapidly delivered and retrieved from the coronary arterial segment to be treated. The delivery catheter is positioned by advancing it over the same guidewire used during the immediately preceding PTCA procedure. The radiation sources are delivered and retrieved through a dual-lumen closed hydraulic circuit, which uses a fluid-filled standard syringe to create the hydraulic pressure. We currently sell a version of the catheter in the United States that fits over most of the length of the guidewire used in the PTCA procedure, commonly known as an "over the wire" catheter, and our European subsidiaries sell a version that fits over the guidewire for only a small portion of the catheter at its far end, commonly known as a "rapid exchange" catheter.

The Beta-Cath/TM/ System is used in a cath lab by an interventional cardiologist in conjunction with a radiation oncologist. The cardiologist places the delivery catheter into the patient's vasculature until the catheter reaches the targeted site. The radiation oncologist operates the transfer device to deliver the radiation source train hydraulically to the end of the catheter in a matter of seconds. The radiation sources remain at the targeted site for less than five minutes to deliver a predetermined dose of radiation. The radiation sources are then returned by the use of positive hydraulic pressure applied through a different lumen of the delivery catheter. Upon completion of each procedure, the train of radiation sources is stored safely inside the transfer device. At the end of the day, the transfer device is delivered to a designated radiation storage site within the hospital for safekeeping. While the need for a cardiologist and a radiation oncologist is expected to result in incremental physician fees, we believe the Beta-Cath/TM/ System will be cost-effective, principally by reducing the need for costly revascularization procedures often required following treatment of in-stent restenosis.

We believe the Beta-Cath/TM/ System has the following advantages:

- Site-specific Therapy. The Beta-Cath/TM/ System is designed to confine radiation exposure to the targeted intervention area.

- Short Procedure Times. The Beta-Cath/TM/ System is designed to enhance patient safety and comfort, as well as to promote productivity in the cath lab, by delivering the recommended dosage in less than five minutes of radiation exposure per lesion.

- Utilization of Existing PTCA Techniques. Although intracoronary radiation is a new concept in coronary artery disease treatment, the hand-held Beta-Cath/TM/ System is designed to be easily adopted and used by the interventional cardiologist. The Beta-Cath/TM/ System is very similar to other catheter-based tools used by the cardiologist.

- Multiple-Use System. The radiation source train can be reused for numerous patients, due to the long half-life of the isotope and because the source train does not come into contact with the patient's blood. As a result, inventory planning is very straightforward, and last minute treatment decisions can be made.

- Ease of Use and Accuracy of Dosing. The Beta-Cath/TM/ System is a hand-held device that is easy to operate. Because of the long half-life of our

radiation source, prescribed treatment times will remain constant over the approved shelf life of the isotope. Vascular brachytherapy systems that utilize short half-life isotopes are likely to require complex case-by-case dose calculations based on the current decay state of the isotope. In addition, they require frequent inventory replacement due to their short half-lives.

. Designed for Safety. The Beta-Cath/TM/ System utilizes localized beta radiation, which results in total body radiation exposure significantly less than that received during routine x-ray during PTCA or during treatment with a gamma radiation device. Other safety mechanisms include: a closed-source train lumen, special locking mechanisms to connect the delivery catheter to the transfer device and sufficient shielding in the transfer device to protect health care workers from beta radiation exposure. In addition, the beta radiation sources are delivered and, following the administration of the prescribed dose, retrieved hydraulically in a matter of seconds, thereby minimizing exposure to adjacent tissue.

PRODUCT DEVELOPMENT AND CLINICAL TRIALS

The Company is engaged in ongoing product development to introduce new products as simple solutions to complex interventional therapies. In addition we seek to enhance the effectiveness, ease of use, safety and reliability of our Beta-Cath/TM/ System and to expand the applications for which its uses are appropriate.

Research and development expenses, which include the cost of clinical trials, for the years ended December 31, 2001, 2000, and 1999 were approximately $12.8 million, $17.1 million and $22.9 million, respectively. The Company has conducted numerous clinical trials to provide the basis for approval by the FDA of several versions of the Beta-Cath/TM/ System.

Beta-Cath/TM/ System Trials

START 30 Trial.

The first trial to be completed was the "Stent And Radiation Therapy Trial" or START Trial. The START 30 Trial was a randomized, triple-masked, placebo-controlled, multicenter human clinical trial with the primary endpoint of target vessel revascularization ("TVR"), the incidence of an additional revascularization procedure in the vessel originally treated within eight months. The START 30 Trial sought to determine the safety and effectiveness of the 30mm version of the Beta-Cath/TM/ System (30mm System) in treating "in-stent" restenosis. Enrollment in this trial of a total of 476 patients at 51 sites was completed in April 1999. In March 2000, we announced the results of the START Trial showing statistically significant results for patients with "in stent" restenosis treated with the 30mm System when compared to patients treated with placebo. In those patients treated with the 30mm system, the rate of restenosis decreased by 66% at the stented portion of the treated artery and by 36% at a longer section of the artery, beyond that treated with radiation or revascularization methods. The START 30 Trial was the basis for the FDA approval of the 30mm system in November, 2000.

START 40 Trial.

In addition, in June 1999 we initiated the START 40 Trial. This multicenter clinical trial enrolled 207 patients who received vascular brachytherapy using

a 40mm active radiation source train. The START 40 Trial had an identical protocol design to the START 30 Trial and, therefore, we used the START 30 Trial's control group in analyzing the clinical data from the START 40 Trial. The purpose of this trial was to gain regulatory approval for the longer 40mm radiation source train. Enrollment of patients was completed in October 1999. The longer 40mm radiation source train was found to be helpful in addressing clinical concerns over the possibility of "geographic miss" during a vascular brachytherapy procedure. Geographic miss is the failure to delivery radiation to the intended target balloon-injury area either due to poor alignment of the radiation source train with the balloon-induced injury, or using too short a radiation source train compared to the balloon injury.

In November, 2000, results from the analysis of the eight month follow-up angiograms were released. The data, as also seen in START 30, demonstrated significant reduction in restenosis in patients treated with beta radiation. In those patients treated with the 40-millimeter source train with the Beta-Cath/TM/ System, compared to those treated with a placebo, a 63% decrease in the rate of restenosis was observed in the stented portion of the treated artery and a 44% decrease was observed in the longer section of the artery, beyond the area treated with radiation or revascularization methods. The 40mm System received FDA approval in June, 2001.

Beta-Cath/TM/ System Trial

Designed in 1996 and begun in July 1997, the Beta-Cath/TM/ System Trial was the first randomized, multicenter, placebo-controlled study of vascular brachytherapy. The Trial was also the first pivotal study to evaluate intracoronary radiation in the primary prevention of coronary restenosis subsequent to either PTCA ("percutaneous transluminal coronary angioplasty" or "balloon angioplasty") or first time stent placement.

The Beta-Cath/TM/ System Trial was originally designed to enroll 1,100 patients into one of two branches, either the PTCA branch or the Provisional Stent branch. According to the clinical trial protocol, patients enrolled in the Trial were initially treated with balloon angioplasty. If the cardiologist achieved a satisfactory result, the patient would remain in the PTCA branch and then be treated with the Beta-Cath/TM/ System. If balloon angioplasty was sub-optimal, the patient would be entered into the Provisional Stent branch. Prior to stent placement, the patient would be treated with the Beta-Cath/TM/ System, after which a stent would be implanted. All patients were randomized to either an inactive (placebo) or active 30-mm Strontium-90 (beta radiation) source train. Patients returned for follow-up examinations eight months after the vascular brachytherapy procedure.

In March 1999, the Trial's Data Safety and Monitoring Board proposed creating a new stent branch comprised of only those patients receiving a longer duration of anti-platelet therapy (APT), a change first implemented by Novoste in November 1998 to address late stent thrombosis concerns. Patient recruitment continued until September 1999, at which time 1,455 patients had been enrolled into the Trial at 59 investigational sites in North America and Europe.

On March 18, 2001, the Company announced the results of the Beta-Cath/TM/ System Trial. While the primary clinical endpoint of the overall Trial did not demonstrate a significant benefit of beta radiation when the two branches of the Trial (balloon and stent) were combined, beta radiation was shown to significantly reduce the risk of angiographic restenosis in the lesion for patients undergoing either balloon angioplasty or stent implantation, when compared to the placebo group. In the PTCA branch, restenosis in the lesion

segment was significantly reduced by 38% in the group receiving radiation versus placebo. In addition, the effect of beta radiation on all clinical outcomes in the PTCA branch demonstrated a strong positive trend.

The Trial was first analyzed by comparing the clinical outcomes of the total radiation cohort (those receiving either PTCA or a stent with extended APT) to the overall placebo group. Then the data was analyzed by reviewing the PTCA and the stent branches individually.

In this combined group of PTCA and stent patients, those who received beta radiation exhibited modest improvements in their clinical endpoints, although not statistically significant. Upon analysis of the two Trial branches, it was clear that patients in the PTCA branch clinically benefited more from radiation than did those in the Stent branch, thereby leading to a less pronounced effect when the two branches were combined. In the PTCA branch, restenosis in the legion segment was significantly reduced by 38% in the group receiving radiation versus placebo. In addition, the effect of beta radiation on all clinical outcomes in the PTCA branch demonstrated a strong positive trend.

In the Stent branch, angiographic restenosis in the lesion was also reduced significantly (by 36%) as in the PTCA branch; however, radiation did not improve restenosis in the much longer analysis segment. This was likely due to "geographic miss", the mismatch of the radiation source train relative to the placement of the stent, which was implanted after the radiation catheter was removed. In reviewing the clinical endpoints of the Stent branch, the data did not show a beneficial effect of radiation on improving outcomes. The incidence of late thrombosis, however, was the same (1.3%) in both the radiation and the placebo groups, indicating that the extended antiplatelet therapy resolved the problems of thrombosis observed in the original stent branch.

Based upon the clinical outcome of the total radiation cohort the Company determined that the results of the Beta-Cath/TM/ System Trial would be insufficient to support an application for pre-market approval in the U.S. to use our device following balloon angioplasty or previously untreated (de novo) lesions.

Additional Beta-Cath/TM/ System Approvals

During 2001 Novoste applied to the FDA for approval to market two additional Beta-Cath/TM/ System products. The Beta-Cath/TM/ 3.5 French (F) System, Novoste's next generation smaller diameter catheter system, received marketing approval from the FDA on in February, 2002. The Beta-Cath/TM/ 3.5 French (F) System, offered with both a 30mm and 40mm radiation source train, is a smaller diameter vascular brachytherapy catheter

approved for the treatment of in-stent restenosis. Due to its lower profile, the 3.5F System should be able to treat areas unable to be addressed with the current 5F System.

Marketing approval for the 60mm Beta-Cath/TM/ System was received was received from the FDA in March 2002. The 60mm device is designed to treat long, diffuse in-stent restenosis. Approval of the 60-mm device was based on the results of a 139 patient subset (RENO Long) of the 1,098 patient RENO (REgistry NOvoste) European registry trial. An analysis was performed on the RENO Long group and compared to a placebo control group selected from the Washington Radiation for In-Stent Restenosis Trials (WRIST / LONG WRIST (n=94)). Thee data demonstrated a 75% reduction in Target Vessel Revascularization (TVR) rate (14.9% vs. 60.6%) and a 72% reduction in Major Adverse Cardiac Event (MACE)

rate (17.9% vs. 64.9%) for the subset of patients receiving Sr-90 beta radiation compared to this placebo control group. The average lesion length for the RENO Long patient subset was 35.3 mm (site reported) compared to the average lesion length of 28.0 mm in the WRIST / LONG WRIST placebo control group.

New Products and Applications

Future development efforts will focus on modifying the Beta-Cath/TM/ System for use in peripheral applications, such as arterial-venous shunts and the femoral arteries. There can be no assurance that we will be successful in developing these or other products.

Mobile Trial

Novoste developed the CORONA(TM) System to deliver Beta vascular brachytherapy to treat patients with peripheral artery disease (restricted blood flow in the upper legs). The Company believes that there is currently no effective treatment of diffuse peripheral artery disease which can become debilitating, by limiting their ability to walk without pain, for patients who suffer from the disease. Symptomatic peripheral artery disease affects over 1.25 million patients annually in the U.S. The CORONA(TM) System differs from the Beta-Cath(TM) System by the addition of a balloon-based delivery system which allows for the treatment of large 5-8mm vessels with relatively short (3 to 5 minute) treatment times.

In December 2001 Novoste began its More patency with Beta In the Lower Extremity (MOBILE) trial. The MOBILE trial will include 410 patients from 30 sites in North American and Europe. Patients will be randomized to receive either standard percutansous catheter-based revascularization therapy followed by vascular brachytherapy or standard therapy alone. Enrollment is expected to be complete in the second half of 2002 and approval, if received, could be in 2004.

Bravo Trial

In March 2002 Novoste announced that it had submitted an investigational device exemption (IDE) application to the FDA for its CORONA(TM) System to treat arterial-venous dialysis graft stenosis. More than 220,000 people in the U.S. currently undergo long-term dialysis for end stage renal disease and a majority of these patients rely on arterial-venous dialysis grafts for vascular access. Unfortunately, these grafts are associated with a very low patency rate of 40-60% at one year and many of these grafts require interventional therapy to maintain patency. There is evidence that the stenosis is due to intimal hyperplasia formation at the graft site as a result of turbulent blood flow, increased pressure and cyclical stretching of the vein wall, and therefore may be an ideal target for vascular brachytherapy.

The BRAVO (Beta Radiation for treatment of Arterial-Venous graft Outflow) trial IDE, submitted to the FDA for review, will be a prospective, randomized, multi-center, placebo-controlled trial investigating the safety and efficacy of the CORONA(TM) System to treat venous outflow stenosis in arterial-venous dialysis grafts.

The BRAVO trial protocol will include 230 patients who will be randomized between conventional treatment and conventional treatment plus radiation and follow-up will be six months. The trial is expected to be performed in 20 sites in North America. We anticipate completion of the enrollment of the 230 patients in the second half of 2002. Provided the trial is successful we intend to file, in 2003, an application to obtain pre-market approval from the FDA to sell the Corona/TM/ System in the United States for the treatment of venous outflow stenosis in arterial-venous dialysis grafts. Approval from the FDA, if

any, would likely not be obtained for at least one year from filing.

Clinical trials are administered by our clinical and regulatory staff of fourteen people. We also use consultants to monitor the clinical sites and to assist in training and have engaged independent contract research organization and consultants to compile data from the trials and to perform statistical and reimbursement analyses. Novoste may take on the responsibilities of future clinical trials as it seeks to develop additional products or obtains rights to products developed by other companies. There can be no assurances that Novoste will have the manpower or resources to successfully complete these trials.

Sales and Marketing

We have recruited a qualified and experienced field sales, sales management and marketing organization and are selling our products directly in the United States through that organization. At year end, this organization totaled 72 employees.

The Company directs its sales and marketing efforts at prominent domestic and international cardiac catheterization laboratories that perform the majority of the interventional cardiology procedures. The Company believes that prominent cardiac cath labs are generally more likely to keep abreast of and utilize new technologies such as the Beta-Cath/TM/ System for diagnosing and treating restenosis. The Company's sales and marketing strategy includes developing and maintaining a close working relationship with its customers in order to assess and satisfy their needs for products and services. The Company meets with clinicians both in the United States and Europe periodically to share ideas regarding the marketplace, existing products, products under development and existing or proposed research projects.

As part of our strategy to increase the awareness of and acceptance of vascular brachytherapy and the Beta-Cath/TM/ System in cardiac cath labs, the Company also works to develop peer reviewed journal articles authored by leading experts in interventional cardiology, sponsors publication of papers based on research covering the performance and benefits of the Beta-Cath/TM/ System and conducts informational seminars.

Our direct sales activities target all of the medical specialists involved in vascular brachytherapy: cardiologists, radiation therapists and medical physicists, which results in a lengthy sales effort. To reach each of these groups, we are using a multidisciplinary sales force consisting of experienced medical device salespeople, clinical specialists with nursing experience in cardiology, and medical physicists experienced in obtaining licenses for new radioactive medical products. The Company expects future products currently in development will be distributed by the existing sales force, supplemented by additional expertise for the particular application or by additional personnel required to properly support the market.

Manufacturing, Sources of Supply

Our manufacturing operations are required to comply with the FDA's quality systems regulations, which included an inspection of our manufacturing facilities prior to pre-market approval. In addition, certain international markets have quality assurance and manufacturing requirements that may be more or less rigorous than those in the United States. Specifically, we are subject to the compliance requirements of ISO 9001 certification and CE mark directives in order to produce products for sale in Europe. We received ISO 9001/EN 46001 certification from our European notified body in April 1998. We are subject to

periodic inspections by regulatory authorities to ensure such compliance. See "Government Regulation." We conduct quality audits of suppliers and we are establishing a vendor certification program. All suppliers of components must also be in compliance with Novoste's and the FDA's quality systems regulations.

Beta Radiation Source Train Suppliers

We have obtained all of our requirements for our beta radioactive sources to date pursuant to an agreement with a single supplier, Bebig Isotopentechnik und Umweltdiagnostik GmbH, a German corporation.

On June 20, 2001, the Company entered into a new manufacturing and supply agreement (Agreement) with Bebig Isotopen-und Medizintechnik GmbH (Bebig), a German corporation, to manufacture and supply the Company with radioactive sealed Strontium-90 seed trains. The Agreement supercedes all prior agreements with Bebig and neither the Company nor Bebig have any rights or obligations under any of the previous agreements. During each calendar year under the four-year contract, the Company guarantees to pay to Bebig minimum annual payments through 2004 aggregating $5,750,000, including decontamination cost. All product purchases are credited against the annual guaranteed payment. Any product payments in excess of the annual guaranteed payment can be credited against the guaranteed payment of the next year. In the event that the Company does not purchase product to exceed the annual guaranteed payment, the deficiency will be due and payable to Bebig within thirty days after the end of each one-year contract period. At December 31, 2001, the Company exceeded the annual guaranteed payment.

Bebig is required to comply with various regulatory requirements with respect to the supply of radiation sources. Bebig has agreed to manufacture radioactive sources at an agreed-upon base price. In light of the technical expertise and capital investment required to manufacture the radioactive sources and the limited number of manufacturers of Strontium 90, it would be difficult to find an alternate source of supply without significant lead time. Our business, results of operations and financial condition could be materially adversely affected by Bebig's failure to provide us with beta isotopes on a timely basis during the term of the agreement or by our inability to obtain an alternative source of supply on a timely basis and on terms satisfactory to us following any termination of the agreement. In addition, portions of the process used to manufacture the materials may be proprietary to Bebig.

On October 14, 1999 the Company signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH for a second source of radioactive supply and for the development of a smaller diameter radiation source. The agreement provides for the construction of a production line which is expected to be finished in two phases. The first phase was completed in February 2001 and the second phase is expected to be completed in mid 2002. The cost of this production line is estimated at $4,000,000 and is paid as construction progresses. Payments made toward the production line are being capitalized as property and equipment. Depreciation of the production line will begin when the equipment is placed into service, expected to be mid 2002. In addition, the agreement provides for joint ownership of all intellectual property arising from the development work and that AEA may manufacture vascular brachytherapy sources only for us. The development of the smaller diameter source may not be successfully completed, the new production line may not be completed on time or on budget, and the smaller diameter source may not be manufacturable in commercial quantities.

Supply of Other Components by Third Parties

We currently rely on third party manufacturers for the supply of the hand-held transfer device and other components of our Beta-Cath/TM/ System. The supply of these components requires a long lead time. In addition, we could not establish quickly additional or replacement suppliers or internal manufacturing capabilities for these components. An existing vendor's failure to supply components in a timely manner or our inability to obtain these components on a timely basis from another supplier could have a material adverse effect on our ability to manufacture the Beta-Cath/TM/ System and, therefore, on our ability to market the Beta-Cath/TM/ System.

Patents and Proprietary Technology

Our policy is to protect our proprietary position by, among other methods, filing United States and foreign patent applications. On November 4, 1997 we were issued United States Patent No. 5,683,345, on May 4, 1999 we received United States Patent No. 5,899,882 (which is jointly owned by us and Emory University) and on January 11, 2000 we received United States Patent No. 6,013,020, all related to the Beta-Cath/TM /System. We also have several additional United States applications pending covering aspects of our Beta-Cath/TM/ System. The United States Patent and Trademark Office has indicated that certain claims pending in another United States application are allowable. With respect to the above identified United States Patents and our other pending United States patent applications, we have filed, or will file in due course, counterpart applications in the European Patent Office and certain other countries.

Like other firms that engage in the development of medical devices, we must address issues and risks relating to patents and trade secrets. United States Patent No. 5,683,345 may not offer any protection to us because competitors may be able to design functionally equivalent devices that do not infringe this patent. It may also be reexamined, invalidated or circumvented. In addition, claims under our other pending applications may not be allowed, or if allowed, may not offer any protection or may be reexamined, invalidated or circumvented. In addition, competitors may have or may obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products in either the United States or international markets.

We received a letter from NeoCardia, L.L.C., dated July 7, 1995, in which NeoCardia notified us that it was the exclusive licensee of United States Patent No. 5,199,939, or the Dake patent, and requested that we confirm that our products did not infringe the claims of the Dake patent. On August 22, 1995 our patent counsel responded on our behalf that we did not infringe the Dake patent.

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

In May 1997 Guidant acquired NeoCardia together with the rights under the Dake patent. Guidant is attempting to develop and commercialize products that may compete with the Beta-Cath/TM/ System and has significantly greater capital resources than the Company. Guidant may sue for patent infringement in an attempt to obtain damages from us and/or injunctive relief restraining us from commercializing the Beta-Cath/TM/ System in the United States. While the

Company does not believe such an action would have merit, if Guidant were successful in any such litigation, we might be required to obtain a license from Guidant under the Dake patent to market the Beta-Cath/TM/ System in the United States, if such license were available, or be prohibited from selling the Beta-Cath/TM/ System in the United States. Any of these actions could have a material adverse effect on our business, financial condition and results of operations, or could result in cessation of our business.

We have two versions of our delivery catheter: a "rapid exchange" catheter and an "over the wire" catheter. As a result of certain United States patents held by other device manufacturers covering "rapid exchange" catheters, we currently intend to sell the "over the wire" version of our delivery catheter in the United States. If further investigation reveals that we may sell a "rapid exchange" version in the United States without infringing the valid patent rights of others, we might decide to do so in the future. However, we cannot assure that we will be able to sell a "rapid exchange" version in the United States without a license of third party patent rights or that such a license would be available to us on favorable terms or at all.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. There can be no assurance that we will not become subject to patent-infringement claims or litigation or interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions. The defense and prosecution of intellectual property suits, or interference proceedings and related legal and administrative proceedings are both costly and time-consuming. Litigation may be necessary to enforce our patents, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings will result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties, require us to seek licenses from third parties, require us to redesign our products or processes to avoid infringement or prevent us from selling our products in certain markets, if at all. Although patent and intellectual property disputes regarding medical devices have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include significant ongoing royalties. Furthermore, there can be no assurance that the necessary licenses would be available to us on satisfactory terms, if at all, or that we could redesign our products or

processes to avoid infringement. Any adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, financial condition and results of operations.

Patent applications in the United States and patent applications in foreign countries are maintained in secrecy for a period after the earliest claimed priority date. Publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries and the filing of related patent applications. Patents issued and patent applications filed relating to medical devices are numerous. Accordingly, there can be no assurance that current and potential competitors, many of which have substantial resources and have made substantial investments in competing technologies, or other third parties have not or will not file applications for, or have not or will not receive, patents and will not obtain additional proprietary rights relating to products made, used or sold or processes used or proposed to be used by us.

We have developed certain of our patent and proprietary rights relating to the Beta-Cath/TM/ System in conjunction with Emory University Hospital, a leader in the research of intravascular radiation therapy. To obtain the exclusive rights to commercialize the Beta-Cath/TM/ System for the treatment of restenosis, we entered into a license agreement with Emory. Under this agreement, Emory assigned to us all of Emory's rights to one United States patent application and exclusively licensed to us its rights under another United States application and related technology. Emory made no representation or warranty with respect to its ownership of the assigned patent application, and made only limited representations as to its ownership of the licensed patent application and related technology. Under the agreement Emory will be entitled to royalty payments based upon net sales of the Beta-Cath/TM/ System. The term of the agreement runs through the later of (i) the date the last patent covered by the agreement expires or (ii) January 2016 (unless earlier terminated as provided in the agreement). Any inventions developed jointly by our personnel and Emory during the term of the license agreement are owned jointly by Emory and us. If Emory terminated the agreement as a result of our failure to pay such royalties or any other breach of our obligations under such agreement, our rights to use jointly owned patents (including the United States Patent No. 5,899,882) would become non-exclusive and we would have no rights to use future patents owned exclusively by Emory. In addition, if we breach our obligations under the license agreement, we could be required by Emory to cooperate in licensing the pending jointly-owned United States patent application and our foreign counterparts to third parties so that they would be able to commercialize and sell the Beta-Cath/TM/ System.

All of the physicians on staff at Emory who were involved in the development of the Beta-Cath/TM/ System, including Spencer B. King III, M.D., have assigned their rights in the technology, if any, to Emory and/or us. In addition, we have entered into a license agreement with Dr. King. Under the terms of this agreement, Dr. King is entitled to receive a royalty on the net sales of the Beta-Cath/TM/ System (excluding consideration paid for the radioactive isotope), subject to a maximum of $5,000,000.

We employ a full time manager of intellectual property to prepare invention records and to coordinate the prosecution of new intellectual property. We typically obtain confidentiality and invention assignment agreements in connection with employment, consulting and advisory relationships. These agreements generally provide that all confidential information developed or made known to the individual by us during the course of the individual's relationship with us, is to be kept confidential and not disclosed to third parties, except in specific circumstances. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of such information or inventions.

Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our proprietary technology, and we may not be able to meaningfully protect our rights in unpatented proprietary technology.

COMPETITION; RAPID TECHNOLOGICAL CHANGE

Competition in the medical device industry, and specifically the markets for cardiovascular devices, is intense and characterized by extensive research and development efforts and rapidly advancing technology. New developments in technology could render vascular brachytherapy generally or the Beta-Cath/TM/

System in particular noncompetitive or obsolete.

Vascular brachytherapy may compete with other treatment methods designed to improve outcomes from coronary artery procedures that are well established in the medical community, such as coronary stents. Stents are the predominant treatment currently utilized to reduce the incidence of coronary restenosis following PTCA and were used in approximately 75% of all PTCA procedures performed worldwide in 2001. Manufacturers of stents include Johnson & Johnson (J&J), Medtronic, Inc., Guidant Corporation and Boston Scientific Corporation. Stent manufacturers often sell many products used in the cardiac catheterization labs, commonly referred to as cath labs, and as discussed below, certain of these companies are marketing vascular brachytherapy devices.

Both J&J and Guidant compete directly with Novoste for market acceptance of vascular brachytherapy and both have substantially greater capital resources and greater resources and experience at introducing new products than does Novoste. J&J's product, the CHECKMATE/TM/ System, is a gamma radiation vascular brachytherapy device. Although, the CHECKMATE/TM/ System received approval at the same time as Novoste's Beta-Cath/TM/ System, the Company believes it competes effectively against J&J because of the ease of use of beta radiation over gamma. In November 2001, Guidant received FDA approval of the GALILEO/TM/ Intravascular Radiotherapy System. The GALILEO/TM/ System is also a beta radiation system as is the Beta-Cath/TM/ System. In the current environment of managed care, economically motivated buyers, consolidation among health care providers, increased competition from J&J and Guidant, Novoste may be required to compete on the basis of price. We may not be able to compete effectively against Guidant or Johnson and Johnson in the future.

Many of these same companies and others are researching coatings and treatments to coronary stents that could reduce restenosis and would possibly be more acceptable to a medical community already experienced at using stents. Recently, results from early human clinical trials were reported as eliminating restenosis. More extensive U.S. clinical trials will need to be completed in order to receive approval to market domestically and, if successful, could have a negative impact on the ultimate acceptability of vascular brachytherapy, our revenue and the Company's stock price. If the trials are successfully completed in the time frame contemplated by at least one competitor, Johnson & Johnson, drug coated stents could receive FDA approval by as early as 2003.

Many of our competitors and potential competitors have substantially greater capital resources than we do and also have greater resources and expertise in the area of research and development, obtaining regulatory approvals, manufacturing and marketing. Our competitors and potential competitors may succeed in developing, marketing and distributing technologies and products that are more effective than those we will develop and market or that would render our technology and products obsolete or noncompetitive. Additionally, many of the competitors have the capability to bundle a wide variety of products in sales to cath labs. We may be unable to compete effectively against such competitors and other potential competitors in terms of manufacturing, marketing, distribution, sales and servicing.

Any product we develop that gains regulatory clearance or approval will have to compete for market acceptance and market share. An important factor in such competition may be the timing of market introduction of competitive products. Accordingly, we expect the relative speed with which we can develop products, gain regulatory approval and reimbursement acceptance and supply commercial quantities of the product to the market to be an important competitive factor. In addition, we believe that the primary competitive factors for products addressing restenosis include safety, efficacy, and ease of use, reliability, and suitability for use in cath labs, service and price. We also believe that physician relationships, especially relationships with leaders in the interventional cardiology and radiation oncology communities, are important

competitive factors.

Government Regulation

United States

Our Beta-Cath/TM/ System is regulated in the United States as a medical device. The manufacture and sale of medical devices intended for commercial distribution are subject to extensive governmental regulations in the

United States. Medical devices are regulated in the United States by the FDA under the Federal Food, Drug and Cosmetic Act (the "FDC Act") and generally require pre-market clearance or pre-market approval prior to commercial distribution. In addition, certain material changes or modifications to medical devices also are subject to FDA review and clearance or approval. The FDA regulates the clinical testing, manufacture, packaging, labeling, storage, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing approvals, a recommendation by the FDA that we not be permitted to enter into government contracts, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed.

In the United States, medical devices are classified into one of three classes (Class I, II or III) on the basis of the controls deemed necessary by the FDA to reasonably assure their safety and effectiveness. Under FDA regulations Class I devices are subject to general controls (for example, labeling, pre-market notification and adherence to good manufacturing practices or quality systems regulations) and Class II devices are subject to general and special controls (for example, performance standards, postmarket surveillance, patient registries, and FDA guidelines). Class III is the most stringent regulatory category for medical devices. Generally, Class III devices are those that must receive pre-market approval by the FDA after evaluation of their safety and effectiveness (for example, life-sustaining, life-supporting or implantable devices, or new devices that have not been found substantially equivalent to other Class II legally marketed devices). The Beta-Cath/TM/ System is a Class III device, which required the FDA's pre-market approval prior to its commercialization, which occurred November 2000.

A pre-market approval application must be supported by valid scientific evidence, which typically includes extensive data, including preclinical and human clinical trial data to demonstrate safety and effectiveness of the device. If human clinical trials of a device are required and the device trial presents a "significant risk," the sponsor of the trial, usually the manufacturer or the distributor of the device, is required to file an investigational device exemption application with the FDA and obtain FDA approval prior to commencing human clinical trials. The investigational device exemption application must be supported by data, typically including the results of animal and laboratory testing. If the investigational device exemption application is approved by the FDA and one or more appropriate Institutional Review Boards, or "IRBs," human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA.

The pre-market approval application must also contain the results of all

relevant bench tests, laboratory and animal studies, a complete description of the device and its components, and a detailed description of the methods, facilities and controls used to manufacture the device. In addition, the submission should include the proposed labeling, advertising literature and training methods (if required).

If the FDA's evaluation of the pre-market approval application is favorable, the FDA will either issue an approval letter or an "approvable letter," containing a number of conditions, which must be satisfied in order to secure the final approval of the pre-market approval application. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a letter approving a pre-market approval application authorizing commercial marketing of the device for certain indications. If the FDA's evaluation of the pre-market approval application or manufacturing facilities is not favorable, the FDA will deny approval of the pre-market approval application or issue a "not approvable letter." The FDA may also determine that additional clinical trials are necessary, in which case approval of the pre-market approval application could be delayed for several years while additional clinical trails are conducted and submitted in an amendment to the pre-market approval application.

The process of obtaining a pre-market approval and other required regulatory approvals can be expensive, uncertain and lengthy, and we may be unsuccessful in obtaining approvals to market future products. The

Company anticipates submitting applications for pre-market approval for the use of radiation in treating femoral-popliteal (fem-pop) disease and arterial-venous (A-V) dialysis grafts after the completion of their respective clinical trials. The FDA may not act favorably or quickly on any of our submissions to the FDA. We may encounter significant difficulties and costs in our efforts to obtain additional FDA approvals that could delay or preclude us from selling new products in the United States. Furthermore, the FDA may request additional data or require that we conduct further clinical studies, causing us to incur substantial cost and delay. In addition, the FDA may impose strict labeling requirements, onerous operator training requirements or other requirements as a condition of our pre-market approval, any of which could limit our ability to market new products. Labeling and marketing activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. FDA enforcement policy strictly prohibits the marketing of FDA cleared or approved medical devices for unapproved uses, further, if a company wishes to modify a product after FDA approval of a pre-market approval, including any changes that could affect safety or effectiveness, additional approvals will be required by the FDA. Such changes include, but are not limited to: new indications for use, the use of a different facility to manufacture, changes to process or package the device, changes in vendors to supply components, changes in manufacturing methods, changes in design specifications and certain labeling changes.

Any products we manufacture or distribute pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the use of the device. Device manufacturers are required to register their establishments and list their devices with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and those state agencies. The Food, Drug and Cosmetic Act requires device manufacturers to comply with good manufacturing practices regulations. A new set of regulations, called the quality systems regulations, went into effect June 1, 1997. The regulations require that medical device manufacturers comply with various quality control

requirements pertaining to design controls, purchasing contracts, organization and personnel; device and manufacturing process design; buildings, environmental control, cleaning and sanitation; equipment and calibration of equipment; medical device components; manufacturing specifications and processes; reprocessing of devices; labeling and packaging; in-process and finished device inspection and acceptance; device failure investigations; and recordkeeping requirements including compliance files. The FDA enforces these requirements through periodic inspections of medical device manufacturing facilities. In addition, a set of regulations known as the medical device reporting regulations obligates manufacturers to inform the FDA whenever information reasonably suggests that one of its devices may have caused or contributed to a death or serious injury, or when one of its devices malfunctions and, if the malfunction were to recur, the device would be likely to cause or contribute to a death or serious injury.

Labeling and promotional activities are also subject to scrutiny by the FDA. Among other things, labeling violates law if it is false or misleading in any respect or it fails to contain adequate directions for use. Moreover, any labeling claims that exceed the representations approved by the FDA will violate the Food, Drug and Cosmetic Act.

Our product advertising is also subject to regulation by the Federal Trade Commission under the Federal Trade Commission Act, which prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce, including the dissemination of any false advertisement pertaining to medical devices. Under the Federal Trade Commission's "substantiation doctrine," an advertiser is required to have a "reasonable basis" for all product claims at the time claims are first used in advertising or other promotions.

Our business involves the import, export, manufacture, distribution, use and storage of Strontium-90 (Strontium/Yttrium), the beta-emitting radioisotope utilized in the Beta-Cath/TM/ System's radiation source train. Accordingly, manufacture, distribution, use and disposal of the radioactive material used in the Beta-Cath/TM/ System in the United States will be subject to federal, state and/or local rules relating to radioactive material. The State of Georgia Department of Natural Resources (DNR) issued a sealed source and device registration certificate for the Company's Beta-Cath/TM/ System on August 4, 2000, allowing it to be listed on the Nuclear Regulatory Commission's Sealed Source and Device Registry. The DNR authorized Novoste to commercially distribute its radiation sources to licensed recipients in the United States with the issuance of a license allowing

the manufacturing and distribution of the Beta-Cath/TM/ System. In addition, we must comply with NRC, Georgia and United States Department of Transportation regulations on the labeling and packaging requirements for shipment of radiation sources to hospitals or other users of the Beta-Cath/TM/ System.

Hospitals in the United States are required to have radiation licenses to hold, handle and use radiation. Many of the hospitals and/or physicians in the United States are required to amend their radiation licenses to include Strontium-90 prior to receiving and using our Beta-Cath/TM/ System. Depending on the state that the hospital is located in, its license amendment will be processed at the DNR in agreement states, or by the NRC. Obtaining any of the foregoing radiation-related approvals and licenses can be complicated and time consuming and may take longer in the NRC States (sixteen states).

We are also subject to numerous federal, state and local laws relating to

such matters as safe working conditions, manufacturing practices, environmental protection, fire-hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with such laws and regulations now or in the future and such laws or regulations could have a material adverse effect upon our ability to do business.

Changes in existing requirements or adoption of new requirements or policies could adversely affect our ability to comply with regulatory requirements. Our failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition or results of operations. We may be required to incur significant costs to comply with laws and regulations in the future and these laws and regulations could have a material adverse effect upon our business, financial condition or results of operations.

International

We qualified to apply CE marking to the Beta-Cath/TM/ System in August 1998, which allows us to sell the device in the 18 countries of the European Economic Area, or EEA, and Switzerland. Although the medical devices directive is intended to ensure free movement within the EEA of medical devices that bear the CE marking, many countries in the EEA have imposed additional requirements, such as labeling in the national language and notification of placing the device on the market. In addition, regulatory authorities in European countries can demand evidence on which conformity assessments for CE-marked devices are based and in certain circumstances can prohibit the marketing of products that bear the CE marking. Many European countries maintain systems to control the purchase and reimbursement of medical equipment under national health care programs, and the CE marking does not affect these systems.

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

The time required to obtain approval for sale in foreign countries may be longer or shorter than that required for FDA approval, and the requirements may differ. The European Union has promulgated rules requiring that medical devices placed on the market after June 14, 1998 bear CE marking, a legal symbol attesting to compliance with the appropriate directive which, in our case, is the medical devices directive. The Company's products have not received regulatory approval in Japan nor have they been approved for government reimbursement in Japan.

In addition, there are generally foreign regulatory barriers other than pre-market approval (including separate regulations concerning the distribution, use, handling and storage of radiation sources), and the export of

devices must be in compliance with FDA regulations. The distribution and use of the Beta-Cath/TM/ System outside the United States is subject to radiation

regulatory requirements that vary from country to country and sometimes vary within a given country. Generally, each country has a national regulatory agency responsible for regulating the safe practice and use of radiation in its jurisdiction. In addition, each hospital desiring to use the Beta-Cath/TM/ System is generally required to amend its radiation license to hold, handle and use the Strontium 90 sources in our device. Generally, these licenses are specific to the amount and type of radioactivity utilized. In addition, generally the use of a radiation source by a physician, either for a diagnostic or therapeutic application, also requires a license, which again is specific to the isotope and the clinical application.

The adoption of the Beta-Cath(TM) System in the European market was not as rapid as the U.S. market adoption. In order to improve profitability and continue to focus on the markets with the greatest opportunity to generate revenue growth, the Company elected to restructure European operations in the fourth quarter of 2001. As a result, Novoste reduced its workforce by thirteen employees in Europe and consolidated its operations into one office located in Germany.

Health Care Cost Containment and Third Party Reimbursement

Our products typically are purchased by clinics and hospitals, which bill various third-party payors, such as governmental programs and private insurance plans, for the healthcare services provided to their patients. Third-party payors carefully review and increasingly challenge the prices charged for medical products and services. Reimbursement rates from private companies vary depending on the procedure performed, the third-party payor, the insurance plan, and other factors. Medicare reimburses hospitals a prospectively determined fixed amount for the costs associated with an in-patient hospitalization based on the patient's discharge diagnosis, and reimburses physicians a prospectively determined fixed amount based on the procedure performed, regardless of the actual costs incurred by the hospital or physician in furnishing the care and unrelated to the specific devices used in that procedure. Medical and other third-party payors are increasingly scrutinizing whether to cover new products and the level of reimbursement for covered products. After the Company develops a promising new product, the Company may find limited demand for it unless the Company obtains reimbursement approval from private and governmental third-party payors.

In international markets, reimbursement by private third party medical insurance providers, including government insurers and providers, varies significantly country by country. In certain countries, the Company's ability to achieve significant market penetration may depend upon the availability of third party governmental reimbursement.

We believe that reimbursement in the future will be subject to increased restrictions such as those described above, both in the United States and in foreign markets. We believe that the overall escalating cost of medical products and services has led to and will continue to lead to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including products we offer. In the United States or foreign markets third-party reimbursement and coverage may not be available or adequate, current reimbursement amounts may be decreased in the future and future legislation, regulation, or reimbursement policies of third-party payors could have a material adverse affect on the demand for our products or our ability to sell our products on a profitable basis, particularly if our system is more expensive than competing products or procedures. If third-party payor coverage or reimbursement is unavailable or inadequate, our business, financial condition, and results of operations could be materially adversely affected.

Product Liability and Insurance

Our business entails the risk of product liability claims. Although we have not experienced any product liability claims to date, such claims could be asserted and we may not have sufficient resources to satisfy any liability resulting from such claims. We maintain product liability insurance with coverage of an annual aggregate maximum of $11 million. Product liability claims could exceed such insurance coverage limits, such insurance may not continue to be available on commercially reasonable terms or at all, and a product liability claim could have a material adverse affect on our business, financial condition or results of operations.

Employees and Consultants

As of December 31, 2001 we directly employed 293 full-time individuals. Most of our employees have prior experience with medical device or pharmaceutical companies. We believe that we maintain good relations with our employees. None of our employees is represented by a union or covered by a collective bargaining agreement. Our success will depend in large part upon our ability to attract and retain qualified employees. We face competition in this regard from other companies, research and academic institutions and other organizations.

We maintain continuing relationships with a number of independent consultants that have contributed to the development of our products and work on specific development projects. These relationships are integral to our continued success and the generation of new products from the research and development departments.

Additional Risk Factors

Dependence on the Successful Commercialization of The Beta-Cath/TM/ System

We began to commercialize the Beta-Cath/TM/ System in the United States in November 2000. Substantially all of our revenue in 2001 was from sales in the United States. We anticipate that for the foreseeable future we will be solely dependent on the successful commercialization of the Beta-Cath/TM/ System. Our failure to continue commercialization of the Beta-Cath/TM/ System would have a material adverse effect on our business, financial condition and results of operations.

The Beta-Cath/TM/ System generated substantial revenue for Novoste in 2001, however, in the future we may be unable to demonstrate that the Beta-Cath/TM/ System is an attractive and cost-effective alternative or complement to other procedures, including coronary stents, competing vascular brachytherapy devices, or drug coated stents. Because the Beta-Cath/TM/ System is our sole near-term product focus, we could be required to cease operations if new technology rendered vascular brachytherapy uncompetitive.

Dependence on Key Personnel

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

materially adversely affect our business, financial condition and results of operations.

The Company's co-founder and Chairman of the Board of Directors is currently serving as CEO in a part-time capacity. While a search is currently underway for a permanent CEO, there can be no assurances that the Company will be able to attract and hire someone to fill the position.

Issuance of Preferred Stock May Adversely Affect Rights of Common Shareholders or Discourage a Takeover

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 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.

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.

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.

Other Provisions Discouraging a Takeover

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

Price Volatility and Fluctuations in Operating Results

The market price of our common stock could decline below the public offering price. Specific factors relating to our business or broad market fluctuations may materially adversely affect the market price of our common stock. The trading price of our common stock could be subject to wide fluctuations in

response to quarter-to-quarter variations in operating results, announcements of technological innovations, new products or clinical data announced by us or our competitors, governmental regulatory action, developments with respect to patents or proprietary rights, general conditions in the medical device or cardiovascular device industries, changes in earnings estimates by securities analysts, or other events or factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations, which have particularly affected the market prices of many medical device companies and which have often been unrelated to the operating performance of such companies. Our revenue or operating results in future quarters may be below the expectations of securities analysts and investors. In such an event, the price of our common stock would likely decline, perhaps substantially. During the twelve month period ended December 31, 2001, the closing price of our common stock ranged from a high of $38.8750 per share to a low of $5.73 per share and ended that period at $8.74 per share.

In addition, our results of operations may fluctuate significantly from quarter to quarter and will depend upon numerous factors, including product development efforts, actions relating to regulatory and reimbursement matters, progress and costs related to clinical trials, the extent to which our products gain market acceptance, and competition. These factors may cause the price of our stock to fluctuate, perhaps substantially.

ITEM 2. PROPERTIES

The Company's facilities are located in Norcross, Georgia and consist of two separate locations totaling approximately 70,000 square feet of leased office and manufacturing space, including a 1,700 square foot class 100,000 clean room. The Company plans to eliminate its Brussels, Belgium office in early 2002 and to move its European office to Krefeld, Germany. The Krefeld, Germany office is leasing approximately 3,000 square feet.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable

ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers and directors are as follows:

Name	Age	Position
Thomas D. Weldon.....	46	Chairman and Chief Executive Officer
Donald J. Webber.....	39	Chief Operating Officer
Edwin B. Cordell, Jr.	43	Chief Financial Officer
Richard diMonda.....	51	Vice President, Clinical Research
David C. Field.....	44	Vice President, New Technology
Daniel G. Hall.....	56	Vice President, General Counsel and Secretary
Adam G. Lowe.....	39	Vice President, Quality Assurance and Regulatory Affairs
Susan D. Smith.....	52	Vice President, Human Resources
Robert P. Walsh.....	38	Vice President, Marketing and Investor Relations

Robert N. Wood, Jr... 47 Vice President, Global Sales

Thomas D. Weldon. Mr. Weldon, co-founded the Company and has served as a Director since our capitalization in May 1992. In June 1998, Mr. Weldon became Chairman of the Company. From May 1992 through March 1999, Mr. Weldon has served as Chief Executive Officer of the Company. In April 1999, he co-founded The Innovation Factory, a medical device venture, where he currently serves as Chairman. In December, 2001, Mr. Weldon resumed the duties of Chief Executive Officer on a part-time basis. Mr. Weldon co-founded and was President, Chief Executive Officer and a Director of Novoste Puerto Rico, Inc., a manufacturer of disposable cardiovascular medical devices, from 1987 to May 1992, prior to its sale. Previous responsibilities included management positions at Arthur Young & Company and Key Pharmaceuticals. Mr. Weldon received a B.S. in Industrial Engineering form Purdue University and an M.B.A. in Operations and Systems Management from Indiana University.

Donald J. Webber. Mr. Webber joined the Company in March 1998 as Director of Manufacturing and served as our Vice President, Manufacturing since January 2000. In January 2002 he was promoted to the position of Chief Operating Officer. From July 1996 through March 1998, Mr. Webber worked for Abiomed, Inc., a manufacturer of cardiac products, as Director of Operations. From January 1995 to July 1996, Mr. Webber was employed by Cabot Medical Corporation, a medical device manufacturer, as Plant Manager and from 1988 to 1995 he was employed by Cordis Corporation, a manufacturer of cardiovascular products. Mr. Webber received an MBA from Nova Southeastern University and a B.S. degree in Industrial Engineering from the State University of New York, Binghamton.

Edwin B. Cordell, Jr. Mr. Cordell joined the company in May 2000 as Vice President of Finance and Chief Financial Officer. From November 1994 through April 2000, Mr. Cordell was Vice President of Finance and Chief Financial Officer of CryoLife Inc. (NYSE: CRY), a producer of implantable living human tissues and adhesives for surgical use. From August 1987 to November 1994, Mr. Cordell served as Controller and Chief Financial Officer of Video Display Corporation, a publicly held consumer electronics manufacturing and distribution company. Mr. Cordell, a CPA, received his B.S. in Accounting from the University of Tennessee.

Richard diMonda. Mr. diMonda joined the Company in September of 1997 as a consultant in January 1998 as Senior Director of Strategic Marketing and has served as our Vice President of Marketing since April of 2000. From March 1987 through August 1997, Mr. diMonda worked for Dornier Medical Systems, Inc., as Director of Corporate Development. From April 1976 to March 1987, Mr. diMonda was employed by American Hospital Association as Director, Division of Clinical Services and Technology. Mr. diMonda received an MBA from Keller Graduate School of Management, a M.S. degree in Biomedical Engineering from Drexel University, and a Bachelor of Electrical Engineering from Villanova University.

David C. Field. Mr. Field joined the Company in April 2001 as Vice President, Peripheral Business. Prior to joining Novoste, Mr. Field served as Director of Business Development for the Peripheral Technologies Division of Bard. From 1995 to 1998 he was the Director of Marketing for the same division of Bard. Earlier in his career

David was Territory Manager for Medi-Tech Inc. a division of Boston Scientific. He holds a B.S. in Business Management form the University of Maryland and an A.D. in Engineering from the State University of New York in Canton.

Daniel G. Hall. Mr. Hall joined the Company in June 2000 as Vice President and General Counsel. He served as vice president, secretary and general counsel of Cordis Corporation beginning in 1981 until the company was acquired by Johnson & Johnson in 1995. From 1995 to 1999, Mr. Hall managed his own private law practice. From June 1999, he practiced with Feldman, Gale & Weber, P.A. in Miami, Florida, serving as managing attorney from December 1999 to June 2000.

Adam G. Lowe. Mr. Lowe joined the Company in June 1999 as our Vice President, Quality Assurance. Effective May 2000, Mr. Lowe also took on the additional responsibility of Vice President, Regulatory Affairs. From July 1993 to June 1999 Mr. Lowe worked for various divisions of C.R. Bard, Inc., a diversified medical device manufacturer, having served most recently as the Vice President, Quality at Bard Access Systems, Mr. Lowe received a B.S. in Materials Science and Engineering from North Carolina State University and became an ASQ Certified Quality Engineer in 1992.

Susan D. Smith. Ms. Smith joined Novoste Corporation in March 1996 and was instrumental in forming the Human Resources Department at the "start-up" company. She was promoted to Director of Human Resources in July 1998 and to Vice President in December 2001. She has over 25 years experience in Administration and Human Resource Management. She attended the University of Georgia. Prior to joining Novoste, she served as Human Resources Administrator for Solos Endoscopy and as Office Manager for First Baptist Church Duluth.

Robert P. Walsh. Mr. Walsh joined Novoste Corporation in July 1998 as Director of Marketing. In December 2000 he was promoted to Senior Director of Marketing. From 1996 to 1998, he served as Vice President, Global Marketing for the Angio-Seal(TM) business unit of Sherwood-David & Geck, where he held various marketing positions since his initial employment in 1990. From 1988 to 1990, Mr. Walsh was a cardiovascular clinical sales specialist with SciMed Life Systems, Inc. Earlier in his career, he served as nurse manager of a cardiac catherization laboratory. Mr. Walsh holds a B.A. and M.B.A. from Maryville University in St. Louis, MO.

Robert N. Wood, Jr. Bob Wood joined the company in June 2000 from Perclose, a manufacturer of arterial closure devices that was acquired by Abbott Laboratories in 1999. He served as the Eastern regional sales manager of Perclose from 1997-2000. From 1987-1997, Mr. Wood was employed by Cordis Corporation (a Johnson & Johnson Company), where he held various senior sales management positions, most recently that of national sales manager for Cordis' Endovascular Systems division. He began his career in the medical device business as a sales representative for Medrad, Inc. in 1983.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock has been traded on the Nasdaq National Market (Nasdaq symbol: NOVT) since May 1996. The number of record holders of the Company's Common Stock at March 1, 2002 was 16,315,676 excluding beneficial owners of shares registered in nominee or street name. The Company has not paid any dividends since its inception, other than the distribution of the Shareholder Rights described in Item 1: Issuance Of Preferred Stock May Adversely Affect Rights of Common Shareholders or Discourage a Takeover, and does not intend to pay any dividends in the foreseeable future. Pursuant to the terms of our revolving line of credit we are restricted from paying dividends on our Common Stock.

The range of high and low closing sale prices for the Common Stock is as follows:

Quarter Ended	High	Low
Year Ended December 31, 2000		
March 31, 2000	$48.7500	$17.0000
June 30, 2000	$61.0000	$36.2500
September 30, 2000	$60.8125	$39.1875
December 30, 2000	$43.4375	$22.5000
Year Ended December 31, 2001		
March 31, 2001	$17.8125	$15.5000
June 30, 2001	$25.8000	$24.9500
September 30, 2001	$ 6.2000	$ 5.9000
December 30, 2001	$ 8.7400	$ 8.2100

On February 28, 2002 the last reported sale price for the Common Stock was $6.70.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected financial data are derived from the consolidated financial statements of Novoste Corporation. The data should be read in conjunction with the consolidated financial statements, related notes, and other financial information included herein.

	For the Year Ended December 31,				
	2001	2000	1999	1998	1997
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Net sales and revenues	$69,908	$ 6,530	$ 1,823	$ 19	$ 29
Costs and expenses:					
Cost of sales	19,164	4,258	1,642	117	--
Research and development	12,756	17,119	22,889	21,089	12,873
Sales and Marketing	34,654	15,651	6,606	3,074	1,022
General and administrative	9,324	6,321	3,775	2,528	1,736
Restructuring and other expense	1,214	--	--	--	--
Loss from operations	(7,204)	(36,819)	(33,089)	(26,789)	(15,602)
Interest income (expenses), net	2,095	3,746	2,169	2,127	1,389
Net loss	$(5,109)	$(33,073)	$(30,920)	$(24,662)	$(14,213)
Basic and diluted net loss per share (1)	$ (0.32)	$ (2.13)	$ (2.30)	$ (2.34)	$ (1.64)
Weighted average shares outstanding (1)	16,152	15,517	13,433	10,536	8,665
Consolidated Balance Sheet Data:					
Working capital	$ 40,482	$ 53,742	$ 38,821	$ 21,797	$ 46,064

Total assets.....	82,911	77,073	49,367	29,482	49,796
Long-term liabilities.....	203	401	--	--	--
Accumulated deficit.....	(121,384)	(116,275)	(83,201)	(52,281)	(27,619)
Total shareholder's equity.....	64,728	67,042	43,065	24,517	47,369

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(1) See note 1 to the consolidated financial statements for an explanation of the method used to compute net loss per share.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward Looking Statements

The statements contained in this Form 10-K that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect our views as of the date they are made with respect to future events and financial performance, but are subject to many uncertainties and risks which could cause our actual results to differ materially from any future results expressed or implied by such forward-looking statements. Examples of such uncertainties and risks are discussed under "Item 1--Business" and in this Item 7. Additional risk factors include those that may be set forth in reports filed by the Company from time to time on Forms 10-K, 10-Q and 8-K. We do not undertake any obligation to update any forward-looking statements.

Overview

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

Since our inception through June 30, 2001 we experienced significant losses in each period due to product development and clinical trial costs and, beginning in 2000, the costs of launching the Beta-Cath/TM/ System in the U.S. At December 31, 2001 we had an accumulated deficit of approximately $121.4 million. The Company experienced its first net operating profit in the third quarter of 2001. We expect to maintain an operating profit in 2002 as we continue to allocate resources to leverage our existing manufacturing operations, both internally and with outside vendors, expect our sales and marketing efforts in support of United States market development to level off as a percent of net sales and anticipate that our administrative activities to support our growth will remain at a constant level. At the same time we will continue to conduct clinical trials and research and development projects in order to expand the opportunities for our technology.

The Company also faces intense competition in the field of vascular brachytherapy with companies that have significantly greater capital resources

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

Critical Accounting Policies

The Company's discussion and analysis of its financial condition and results of operations are based upon the Company's 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. Note 1 to the Consolidated Financial Statements discusses all our significant accounting policies.

Revenue Recognition

Revenue from the sale of products is recorded when an arrangement exists, delivery has occurred or services have been rendered, the seller's price is fixed and determinable and collectability is reasonably assured. The Company earns revenue from sales of catheters and from license and lease agreements to use the radiation source trains and transfer devices included in the Beta-Cath(TM) System.

Novoste uses distributors in countries where the distributors experience and knowledge of local radiation and medical device regulatory issues is considered beneficial by the Company's management. Under the distributor arrangements, there are 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 once the hospital has leased a Beta-Cath(TM) System and completed all licensing and other requirements to use the system. The Company recognizes revenue from sales of catheters to distributors at the time of shipment.

The Company retains ownership of the radiation source trains and transfer devices and enters into either a lease or license agreement with its customers. Revenue recognition begins once 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. The terms of the operating lease signed with customers located in

the United States requires, as dictated by FDA regulatory approval, replacement and servicing of the radiation source train and transfer device at six-month intervals. No other post-sale obligations exist.

Radiation and Transfer Devices and Amortization of Costs

The Company retains ownership of the radiation source trains (RSTs) and transfer devices (TDs) that are manufactured by third party vendors. The costs to acquire, test and assemble these assets are recorded as incurred. The Company has determined that based upon experience, testing and discussions with the FDA the estimated useful life of RSTs and TDs exceeds one year and is potentially as long as four years. Accordingly, the Company 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 useful lives, currently 18 months, using the straight-line method. Depreciation begins once the Beta-Cath/TM/ System is placed into service. Valuation allowances are recorded for TDs and RSTs that are not available for use by a customer.

The Company has invested significant resources to acquire RSTs and TDs that make up the Beta-Cath/TM/ System and offers multiple treatment length catheters (each of which requires a different TD and RST). The acquisition of these various length systems are based upon demand forecasts made based upon available information from Sales and Marketing. If actual demand were less favorable or of a different mixture of treatment lengths than those projected by management, additional valuation allowances might be required which would negatively impact operating profits.

Stock Based Compensation

Novoste applies the provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ("SFAS 123"). As permitted by SFAS 123, the Company accounts for stock options grants in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25") and related interpretations. Accordingly, no compensation expense is recognized for

stock option grants to employees for which the terms are fixed. The Company 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.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force (EITF) 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 earns those options.

Allowance for Doubtful Accounts

We maintain 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. If the financial condition of our customers deteriorates, additional allowances may be required. Allowances are also maintained for future sales returns and allowances based on an analysis of recent trends of product returns.

Inventories

Novoste values its inventories at the lower of cost or market 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

Comparison of Years Ended December 31, 2001 and 2000

The net loss for the year ended December 31, 2001 was $5,109,000, or $.32 per share, as compared to $33,073,000, or $2.13 loss per share, for the year earlier. The decrease in net loss for the twelve months ended December 31, 2001 was primarily due to an increase in revenue from sales in the U.S. market from its commercial launch of the Beta-Cath/TM/ System.

Net Sales and Revenues. Net sales and revenues were $69,908,000 for the year ended December 31, 2001 as compared to $6,530,000 for the year ended December 31, 2000. The increase was due to the FDA approval of the Beta-Cath/TM/ System in November 2000 and the initial, first full year of sales in the U.S. Revenues recorded in the United States for the year ended December 31, 2001 were $64,696,793 as compared to $1,816,250 for the year ended December 31, 2000. The increase in revenues was primarily due to the addition of over 300 sites in the U.S. market and the accompanying stocking orders for catheters in these new sites. Typically a new site in the U.S. will order 5 to 10 catheters. Comparatively, international revenue increased 10.6% to $5,211,503 compared to $4,713,331. International sales increased from the prior year due to adding sites in other parts of the world. Non U.S. revenue has not risen at the same rate seen in the United States because of a lack of acceptance of vascular brachytherapy in Europe and no insurance reimbursement approval. The U.S. market received insurance reimbursement for the procedure in the second half of 2001 that contributed to the acceptance and growth in revenue in this market.

Cost of Sales. Cost of sales for the year ended December 31, 2001 were $19,164,000 resulting in a gross margin of $50,744,000 or 73% as compared to cost of sales of $4,258,000 and a gross margin of $2,272,000 or 35% of net sales for the year ended December 31, 2000. The increase in gross margin on both an absolute and percentage basis is due to the higher sales and production volumes and improved production yields during 2001.

The Company expects gross margins to remain relatively stable during 2002 when volume dramatically increases or decreases. Cost of sales includes raw material, labor and overhead to manufacture catheters as well as the amortized costs of transfer devices and radiation source trains used in the Beta-Cath/TM/ System.

Research and Development Expenses. Research and development expenses decreased 25% to $12,756,000 for the twelve months ended December 31, 2001 from $17,119,000 for the twelve months ended December 31, 2000. These decreases were primarily the result of decreased clinical trial activity related to the completion of patient enrollment in the pivotal trials, the largest expense of which was the costs of supplying product to clinical sites. Research and development expenses were favorably impacted by the approval of the Beta-Cath/TM/ System in November 2000. The Company anticipates increasing research and development expenses in 2002 as it pursues product improvements and line extensions, some of which may require additional clinical trials.

Sales and Marketing Expenses. Sales and marketing expenses increased 121% to $34,653,000 for the year ended December 31, 2001 as compared to $15,651,000 for the previous year. These increases were primarily the result of higher personnel, trade show, consulting and promotional literature costs associated with marketing the Company's product on a direct basis in the U.S. and Europe and significant expenses in recruiting, training and retaining a United States sales force for the launch of the Beta-Cath/TM/ System in the United States. The Company expects sales and marketing expenses in 2002 to remain relatively consistent with 2001 expense.

General and Administrative Expenses. General and administrative expenses increased 48% to $9,324,000 for the year ended December 31, 2001 from $6,321,000 for the year ended December 31, 2000. The increase for this twelve month period was primarily the result of additional management personnel at higher salaries and the increase in infrastructure (accounting, information systems, human resources and benefits) to support the commercial launch of the Beta Cath System. The Company expects that at the current level of sales, general and administrative expenses will remain constant in 2002.

Restructuring and Other Expenses. Restructuring charges of $773,000 were recorded in 2001 primarily related to a reduction in workforce of thirteen employees located in Europe and six employees located in the United States in addition to termination of certain facility leases in Europe. The Company paid $560,000 of the restructuring charges in 2001 related to severance payments and lease payments for closed facilities and has $213,000 remaining in accrued expenses at December 31, 2001 related primrily to severance agreements and facility lease and termination payments. The Company expects to save approximately $4,000,000 annually from this restructuring.

During 2001, the Company contributed $440,000 for an 8% ownership interest in an equity method investment. This amount was subsequently expensed as a result of the impairment of that investment.

Interest Income. Net interest income decreased 44% to $2,095,000 for the twelve months ended December 31, 2001 from $3,745,000 for the same period a year earlier. The decrease in interest income year-to-date was primarily due to the decrease in average cash equivalent and short-term investment balances that were used for operations combined with falling interest rates.

Comparison of Years Ended December 31, 2000 and 1999

The net loss for the year ended December 31, 2000 was $33,073,000, or $2.13 loss per share, as compared to $30,920,000, or $2.30 loss per share, for the year earlier. The increase in net loss for the twelve months ended December 31, 2000 was due to increased sales and marketing expenses related to our United States and European operations compared to the prior year. This was partially offset by lower clinical trial expenses during the twelve months ended December 31, 2000. The decrease in the loss per share was due to more shares outstanding in 2000 than in 1999.

Net Sales and Revenues. Net sales and revenues were $6,530,000 for the year ended December 31, 2000 as compared to $1,823,000 for the year ended December 31, 1999. On November 3, 2000, the FDA granted marketing approval for the Company's Beta-Cath/TM/ System in the United States market, and Novoste began immediately marketing the product through its direct sales force. The increase in net sales was primarily due to the increase in number of active sites, including 21 sites that were opened in the United States market, and the increase in utilization rates within these sites as compared to the year earlier period. Within Europe, Germany represented 74% of total company revenues in the twelve months ended December 31, 2000. Internationally, with the exception of the Australian and New Zealand distributors, sales are denominated in Euros. The Euro declined 11% as compared to the year earlier period. The Company's distributor for the markets of Australia, New Zealand and China accounted for 20% of net sales in 2000 compared to 14% in 1999.

The Company earns revenue from sales of catheters and from sales of license and lease agreements to use the radiation source trains and transfer devices included in the Beta-Cath/TM/ System. The Company retains ownership of the radiation source trains and transfer devices and enters into either a one-year lease or license agreement with its customers. Payments under these arrangements are either due in full at the inception of the agreement or over the term of the agreement as catheters are purchased. Revenue recognition begins once an agreement has been executed, the system has been shipped, and all licensing and other requirements to use the system have been completed. The Company is dependent upon market acceptance of the Beta-Cath/TM/ System in the United States.

During 1999 and through the second quarter of 2000, all payments under license agreements were payable at the inception of the agreement. These agreements were accounted for as sales-type leases and, accordingly, revenue and the related costs of sales were recognized upon shipment. Beginning in the third quarter of 2000, after the Company determined the estimated useful life of the system exceeded one year, license and lease agreements were determined to be operating leases and, accordingly, revenue has been recorded over the one year term of the related agreements and costs are recorded over an eighteen month estimated useful life. During 2000 and 1999, approximately $365,000 and $713,000, respectively was earned related to the lease of radiation of transfer devices and is included in net sales.

Cost of Sales. Cost of sales consist primarily of direct labor, allocated manufacturing overhead, third-party contractor costs, royalties and the acquisition cost of raw materials and accessories. Our gross margin in 2000 was $2,272,000, or 35% of net sales, compared to a gross margin of $181,000, or 10% of net sales in 1999. The increase in gross margin on both an absolute and percentage basis is due to the higher sales and production volumes and improved production yields as the Company transitions out of the start-up phase.

Research and Development Expenses. Research and development expenses decreased 25% to $17,119,000 for the twelve months ended December 31, 2000 from $22,889,000 for the twelve months ended December 31, 1999. These decreases were primarily the result of decreased clinical trial expense related to the completion of patient enrollment in the pivotal trials, the largest expense of which was the costs of supplying product to clinical sites. Research and development expenses were favorably impacted by the recent approval of the Beta-Cath/TM/ System.

Sales and Marketing Expenses. Sales and marketing expenses increased 137% to $15,651,000 for the year ended December 31, 2000 as compared to $6,606,000 for the previous year. These increases were primarily the result of higher

personnel, trade show, consulting and promotional literature costs associated with marketing the Company's product on a direct basis in Europe and significant expenses in recruiting, training and retaining a United States sales force for the launch of the Beta-Cath/TM/ System in the United States.

General and Administrative Expenses. General and administrative expenses increased 67% to $6,321,000 for the year ended December 31, 2000 from $3,775,000 for the year ended December 31, 1999. The increase for this twelve month period was primarily the result of additional management personnel and higher salaries and the increase in infrastructure (accounting, information systems, human resources and benefits) to support a commercial company.

Interest Income. Net interest income increased 72% to $3,745,000 for the twelve months ended December 31, 2000 from $2,169,000 for the same period a year earlier. The increase in interest income for the quarter and the year-to-date was primarily due to the increase in average cash equivalent and short-term investment balances arising from the private placement equity offering in March and April 2000, as well as an increase in cash on hand due to a large number of stock option exercises at the end of June, 2000.

Liquidity and Capital Resources

During the years ended December 31, 2001, 2000 and 1999, the Company used cash to fund operations of $3.4 million, $30.3 million and $30.9 million, respectively. The decrease in cash used by operating activities of $26.9 million for 2001 over 2000 was primarily attributable to (i) $8.5 million funding of accounts receivable due to the growth in sales of the Beta-Cath(TM) System related to the initial market launch in the U.S., (ii) $3.7 million used to fund the purchase of increased levels of inventory, (iii) $.3 million decrease in prepaid expenses, (iv) $1.8 million used for payment of accounts payable, and (v) $.1 million decrease in other assets, offset by (i) $28.0 million decrease in net loss, (ii) $6.4 million increase in earnings related to non-cash items, (iii) $4.4 million provided by accrued expenses and taxes withheld, and (iv) $1.6 million increase in unearned revenue related to revenue recognized on radiation and transfer devices.

The decrease in cash used by operating activities of $.6 million for 2000 over 1999 was primarily due to (i) $2.2 million increase in net loss, (ii) $2.9 million funding of accounts receivable due to the growth in sales of the Beta-Cath(TM) System related to the initial market launch in the Europe, (iii) $.2 million decrease in prepaid expenses, (iv) $1.0 million used to pay accrued expenses and taxes withheld, and (v) $.1 million decrease in other assets, offset by (i) $.8 million increase in earnings related to non-cash items, (ii) $3.2 million provided by the decrease in inventory levels, (iii) $2.4 million increase in accounts payable and (iv) $.6 million increase in unearned revenue related to revenue recognized on radiation and transfer devices.

Net cash used by investing activities for the years ended December 31, 2001, 2000 and 1999 was $19.1 million, $6.5 million and $12.7 million, respectively. The $11.7 million decrease in cash used in 2001 compared to 2000 was due to $4.7 million used to purchase short-term investments, $7.5 million used to buy additional radiation and transfer devices related to the increase in demand for our Beta-Cath(TM) System, and $.4 million decrease in funds used to purchase property and equipment.

The $6.2 million increase in cash used in 2000 compared to 1999 was due to $14.3 million in short-term investments that matured, offset by $2.5 million used to purchase property and equipment and $5.6 million used to buy additional

radiation and transfer devices related to the increase in demand for our Beta-Cath(TM) System.

The Company's financing activities include equity offerings and borrowings and repayments of capital leases. Financing activities for the years ended December 31, 2001, 2000 and 1999 provided net cash of $1.7 million, $56.1 million and $48.3 million, respectively.

In 2001, the Company received $1.9 million from the exercise of stock options and repaid $.2 million for capital leases of computer equipment.

On April 7, 2000 the Company completed a private placement offering, in which we sold 1,463,500 shares of our common stock at $35.00 per share. The placement raised net proceeds of approximately $49 million, of which $5 million was received during the second quarter. After the offering, the Company had 15.85 million shares of common stock outstanding. The Company also received approximately $7.2 million during the year from the exercise of stock options. Also during 2000, the Company repaid $.1 million for capital leases of computer equipment.

On March 19, 1999 the Company completed a follow-on public offering of 2,400,000 newly issued shares of its common stock at a public offering price of $20 per share. On March 24, 1999 the Company issued an additional 160,000 shares of common stock pursuant to the exercise of the underwriters' over-allotment option. Net proceeds to the Company after the exercise of the underwriters' over-allotment option and all related expenses totaled $47.4 million. During 1999, the Company also received $.9 million from the exercise of stock options.

At December 31, 2001 the Company had commitments to purchase $7.4 million in inventory components of the Beta-Cath(TM) System over the next year.

In addition, on October 14, 1999 the Company signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH for a second source of radioisotope supply and for the development of a smaller diameter source. This agreement provides for the construction of a production line over the period October 1, 1999 to mid 2002. The cost of this production line is estimated at $4.0 million and is being paid by the Company as construction progresses. Through December 31, 2001, the Company has paid $3.9 million towards this commitment.

On June 20, 2001, the Company entered into a manufacturing and supply agreement (Agreement) with Bebig Isotepen-und Medizintechnik GmbH (Bebig), a German corporation, to manufacture and supply the Company with radioactive sealed Strontium-90 seed trains. The Agreement supercedes all prior agreements with Bebig and neither the Company nor Bebig have any rights or obligations under any of the previous agreements. During each calendar year under the four-year contract, the Company guarantees to pay to Bebig minimum annual payments aggregating $5.5 million. All product purchases are credited against the annual guaranteed payment. Any product payments in excess of the annual guaranteed payment can be credited against the guaranteed payment of the next year. In the event that the Company does not purchase product to exceed the annual guaranteed payment, the deficiency will be due and payable to Bebig within thirty days after the end of each one-year contract period. At December 31, 2001, the Company exceeded the annual guaranteed payment.

Significant proportions of key components and processes relating to the

Company's products are purchased from single sources due to technology, availability, price, quality, and other considerations. Key components and processes currently obtained from single sources include isotopes, protective tubing for catheters, proprietary connectors, and certain plastics used in the design and manufacture of the transfer device. In the event a supply of a key single-sourced material or component was delayed or curtailed, the Company's ability to produce the related product in a timely manner could be adversely affected. The Company attempts to mitigate these risks by working closely with key suppliers regarding the Company's product needs and the maintenance of strategic inventory levels.

The Company has entered into a license agreement with a physician pursuant to which he is entitled to receive a royalty on the net sales of the Beta-Cath/TM/ System (excluding consideration paid for the radioactive isotope), subject to a maximum payment of $5,000,000. Royalty fees to the physician aggregated $632,600, $63,200 and $11,250 in 2001, 2000 and 1999, respectively, and have been expensed in Cost of Sales.

On January 30, 1996, the Company entered into a license agreement whereby Emory University assigned its claim to certain technology to the Company for royalties based on net sales (as defined in the agreement) of products derived from such technology, subject to certain minimum royalties. The royalty agreement term is consistent with the life of the related patent and applies to assignments of the patent technology to a third party. Royalty fees to Emory University aggregated $1,443,967, $146,050 and $36,330 in 2001, 2000 and 1999, respectively, and have been expensed in Cost of Sales.

The Company's principal source of liquidity at December 31, 2001 consisted of cash, cash equivalents and short-term investments of $31.7 million. In August 2001, the Company entered into a $10 million revolving line of credit with a financial institution (lender) that matures in August 2002. At December 31, 2001, there were no outstanding borrowings under this agreement. The Company may borrow an amount not to exceed the borrowing base as defined in the loan agreement. Interest is payable on the first of each month calculated on the outstanding balance and accrues at a rate of the bank's prime rate plus 1%. At such time that the Company sustains three consecutive months of profitability, the rate decreases to the prime rate. The Company granted a first priority security interest in substantially all assets of the Company. Additionally, the loan agreement contains certain financial and non-financial covenants.

In addition, the Company also has Letters of Credit available under the line of credit. The lender will issue or have issued letters of credit for the Company's account not exceeding (i) the lesser of the committed revolving line of the borrowing base minus (ii) the outstanding principal balance of the Advances and minus (iii) the Cash Management Sublimit as defined below; however, the face amount of outstanding Letters of Credit (including drawn but unreimbursed letters of credit) may not exceed $500,000. Each letter of credit will have an expiry date of no later than 180 days after the revolving maturity date, but the Company's reimbursement obligation will be secured by cash on terms acceptable to the lender at any time after the revolving maturity date if the term of this Agreement is not extended by the Lender. The Company agrees to execute any further documentation in connection with the letters of credit as the lender may reasonably request.

The Company may use up to $500,000 for the Lender's Cash Management Sublimit, which may include merchant service, direct deposit of payroll, business credit card, and check cashing services identified in various cash

management services agreements related to such services (the "Cash Management Services"). All amounts the Lender pays for any Cash Management Services will be treated as advances under the committed revolving line. The Company did not have any credit lines or borrowings outstanding at December 31, 2001.

The Company had significant operating losses through the second quarter of 2001 and has been profitable for the remaining two quarters of 2001. The Company believes that existing cash and cash expected to be generated from a operations will be sufficient to meet its working capital, financing and capital expenditure requirements through at least 2002. The Company's future liquidity and capital requirements will depend upon numerous factors, including, among others: market demand for its products; the resources required to maintain a direct sales force in the United States and in the larger markets of Europe, the resources required to introduce enhancements to and expansion of the Beta Cath(TM) System product line; the resources the Company devotes to the development, manufacture and marketing of its products; resources expended to license or acquire new technologies; and the progress of the Company's clinical research and product development programs. Novoste may in the future seek to raise additional funds through bank facilities, debt or equity offering or other sources of capital. Additional financing, if, required, many not be available on satisfactory terms, or at all.

RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 133, Accounting and Reporting for Derivative Instruments. SFAS 133 establishes accounting and reporting standards for derivative and hedging activities. SFAS 133, as amended by SFAS 137 and SFAS 138, was adopted by the Company on January 1, 2001. The adoption of these statements did not have a material impact on the Company's financial statements.

In June 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143 addresses accounting and reporting for obligations associated with the retirement of tangible long-lived assets. SFAS 143 is effective for fiscal years beginning after June 15, 2002. The Company is currently assessing the impact of SFAS 143 on its financial statements.

In June 2001, the FASB issued SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. Under the new rules, goodwill and indefinite lived intangible assets are no longer amortized but are renewed annually for impairment, or move frequently if impairment indictors arise. The adoption of this standard did not have a material impact on the Company's financial statements.

In July 2001, the FASB issued SFAS No. 144, Impairment or Disposal of Long-Lived Assets, which is effective for fiscal years beginning after December 15, 2001. The provisions of this statement provide a single accounting model for impairment of long-lived assets. The Company does not expect that the adoption of SFAS 144 will have a material impact on its financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

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

by the Company. Such guidelines include security type, credit quality and maturity and are intended to limit market risk by restricting the Company's investments to high credit quality securities with relatively short-term maturities.

At December 31, 2001, the Company had $1.7 million in cash equivalents with a weighted average interest rate of 1.8% and $31.7 million in available for sale investments with a weighted average interest rate of 4.07% At December 31, 2000, the Company had $21.7 million in cash equivalents with a weighted average interest rate of 6.32% and $30.7 million in available for sale investments with a weighted average interest rate of 6.67%. All investments mature, by policy, in one year or less.

Foreign Currency Risk

International revenues from the Company's foreign direct sales and distributor sales comprised 7% of total revenues for the year ended December 31, 2001 and 72% for the year ended December 31, 2000. With the exception of the Australian, Chinese and New Zealand distributor, which sales are denominated in U.S. dollars, sales are denominated in Euros. The Company experienced an immaterial amount of transaction gains and losses for the year ended December 31, 2001. The Company 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 the Company during the year ended December 31, 2001 was not material.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements, with the report of the independent auditors, listed in Item 14, are included in this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING FINANCIAL DISCLOSURE

Not applicable.

PART III

Incorporated by reference.

This information required by Part III of this Form 10-K is omitted from this Report in that the Registrant will file a definitive proxy statement pursuant to Regulation 14(a) for its 2001 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Report, and certain information included therein is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information on directors required by Items 401 and 405 of Regulation S-K is incorporated herein by reference to the Company's definitive Proxy Statement ("Proxy Statement"), which will be filed with the Securities and Exchange Commission ("SEC") within 120 days after December 31, 2001.

Information concerning the Company's executive officers required by Item 401(b) of Regulation S-K appears in Part I of this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 402 of Regulation S-K is incorporated herein by reference to the Company's Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2001, except that the Report of the Compensation Committee and the Stock Performance Graph contained in the Proxy Statement are specifically excluded from incorporation by reference herein.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by Item 403 of Regulation S-K is incorporated herein by reference to the Company's Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2001.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by Item 404 of Regulation S-K is incorporated herein by reference to the Company's Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2001.

PART VI

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a)1. Index to Financial Statements.

The following consolidated financial statements of Novoste Corporation are included herein:

2. Financial Statement Schedules.

Information required by consolidated financial statement schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission is included in the Notes to Consolidated Financial Statements; thereby eliminating the needs for these schedules.

3. Exhibits.

The exhibits listed in the accompanying Index to Exhibits immediately following the financial statement schedules are filed with this report.

(b) Reports on Form 8-K.

The following reports were filed on Form 8-K by the Registrant during the fiscal quarter ended December 31, 2001.

(1). The Company filed a Form 8-K on December 28, 2001 stating that it had issued a press release announcing that William A. Hawkins had resigned as the Registrant's President and CEO.

(2). The Company filed a Form 8-K on January 28, 2002 stating that it had initiated a voluntarily recalled 50 Beta-Cath(TM) System transfer devices.

Exhibits--The response to this portion of Item 14 is submitted as a separate section of this report commencing on page 57 of this report.

REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Shareholders
Novoste Corporation

We have audited the accompanying consolidated balance sheets of Novoste Corporation (the "Company") as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2001 and 2000, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Ernst & Young LLP

Atlanta, Georgia
January 28, 2002

NOVOSTE CORPORATION

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2001	20
ASSETS		
Currents assets:		
Cash and cash equivalents	$ 5,878,286	$ 26,
Short-term investments	31,683,627	30,
Accounts receivable, net of allowance of $878,424 and 311,310 respectively (Note 1)	16,130,721	4,
Inventories	3,746,433	1,
Prepaid expenses and other current assets	1,023,137	
Total current assets	58,462,204	63,
Property and equipment, net	9,886,711	7,
Radiation and transfer devices, net	13,534,356	5,
Receivable from officers	144,025	
Other assets	883,311	
	$ 82,910,607	$ 77,
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,026,866	$ 3,
Accrued expenses	10,917,277	5,
Deferred revenue	2,786,476	
Capital lease obligations	249,212	
Total current liabilities	17,979,831	9,
Long-term liabilities:		
Capital lease obligations	203,135	
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; 16,265,081 and 16,094,635 shares issued, respectively	162,651	
Additional paid-in capital	187,357,044	184,
Accumulated other comprehensive income (loss)	(408,139)	
Accumulated deficit	(121,383,528)	(116,
	65,728,028	68,
Less treasury stock, 5,780 shares of common stock at cost	(23,840)	
Unearned compensation	(976,547)	(1,
Total shareholders' equity	64,727,641	67,

	$ 82,910,607	$ 77,

See accompanying notes

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2001	2000	1999
Net sales	$69,908,296	$ 6,529,581	$ 1,823,394
Cost of sales	19,164,436	4,257,602	1,642,395
Gross margin	50,743,860	2,271,979	180,999
Operating expenses:			
Research and development	12,756,257	17,118,976	22,889,182
Sales and marketing	34,653,392	15,650,756	6,606,337
General and administrative	9,324,347	6,321,186	3,775,154
Restructuring and other expense	1,213,705	--	--
Total operating expenses	57,947,701	39,090,918	33,270,673
Loss from operations	(7,203,841)	(36,818,939)	(33,089,674)
Interest income	2,164,295	3,784,378	2,209,983
Interest expense	(75,783)	(22,535)	(13,526)
Other income (expense)	6,488	(16,377)	(26,995)
Total other income	2,095,000	3,745,466	2,169,462
Net loss	$(5,108,841)	$(33,073,473)	$(30,920,212)
Net loss per share--basic and diluted	$ (0.32)	$ (2.13)	$ (2.30)
Weighted average shares outstanding--basic and diluted	16,152,360	15,517,272	13,433,226

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income(Loss)	Accumulated Deficit	Treasury Stock
	Shares	Amount				
Balance at December 31, 1998	10,704,817	$107,048	$ 77,022,814	$ --	$(52,281,002)	$(23,840)
Issuance of stock in secondary offering at $20 per share, net of issuance costs of $3,776,228	2,560,000	25,600	47,398,172	--	--	--
Issuance of restricted stock for compensation to officers, 10,000 shares at $23.56, 25,000 shares at $20.75	35,000	350	754,025	--	--	--
Deferred compensation relating to issuance of certain stock options	--	--	1,792,500	--	--	--
Deferred consulting charges on stock option grants	--	--	234,597	--	--	--
Amortization of unearned compensation and deferred consulting	--	--	112,500	--	--	--
Exercise of stock options at $0.25 to $17.25 per share	901,815	9,018	867,934	--	--	--
Comprehensive income (loss):						
Translation adjustment	--	--	--	57,722	--	--
Net loss	--	--	--	--	(30,920,212)	--
Total comprehensive loss	--	--	--	--	--	--
Balance at December 31, 1999	14,201,632	$142,016	$128,182,542	$57,722	$(83,201,214)	$(23,840)

See accompanying notes.

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NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Income Accumulated Deficit	Treasury Stock
	Shares	Amount				
Issuance of stock in private placement, 1,463,500 shares at $35 per share, net of issuance costs of $2,525,275.....	1,463,500	14,635	48,682,590	--	--	--
Issuance of restricted stock for compensation to officer and employees, 1,500 shares at $41 per share, 1,950 shares at $22.50 per share.....	3,450	35	105,340	--	--	--
Cancellation of unvested equity awards issued to officer.....	(7,500)	(75)	(249,300)	--	--	--
Other equity transactions.....	--	--	114,880	--	--	--
Amortization of unearned compensation.....	--	--	--	--	--	--
Deferred consulting charges on stock option grants.....	--	--	328,876	--	--	--
Exercise of stock options at $1.00 to $29.63 per share.....	426,544	4,265	7,141,874	--	--	--
Issuance of stock under Employee Stock Purchase Plan 3,219 shares at $36.125 and 3,790 shares at $23.375.....	7,009	70	204,808	--	--	--
Comprehensive loss:						
Translation adjustment.....	--	--	--	(151,412)	--	--
Net loss.....	--	--	--	--	(33,073,473)	--
Total comprehensive loss.....	--	--	--	--	--	--
Balance at December 31, 2000.....	16,094,635	$160,946	$184,511,610	$ (93,690)	$(116,274,687)	$(23,840

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Income Accumulated	Treasury	S Un
	Shares	Amount	Capital	Income (Loss)	Deficit	Stock	Comp
Exercise of stock options at $3.20 to $27.00.....	117,188	1,172	1,258,302	--	--	--	
Deferred compensation relating to issuance of stock options to officers.....	--	--	839,361	--	--	--	(5
Issuance of stock under Employee Stock Purchase Plan, 36,776 shares at $14.93 and 12,482 shares at $7.15.....	49,258	493	637,731	--	--	--	
Issuance of restricted stock to an officer (3,000 shares) and consultant (1,000 shares) at $23.02 per share.....	4,000	40	92,040	--	--	--	(
Amortization of unearned..... compensation.....							9
Other equity transactions.....	--	--	18,000	--	--	--	
Comprehensive loss:							
Translation adjustment.....	--	--	--	(314,449)	--	--	
Net loss.....	--	--	--	--	(5,108,841)	--	
Total Comprehensive loss.....	--	--	--	--	--	--	
Balance at December 31, 2001.....	16,265,081	$162,651	$187,357,044	$(408,139)	$(121,383,528)	$(23,840)	$(9

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	2001	2000	1
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (5,108,841)	$(33,073,473)	$(30,
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization of property and equipment	2,413,135	1,458,994	
Amortization of radiation and transfer devices	5,087,576	131,815	
Issuance of stock for services or compensation	244,814	328,876	
Amortization of deferred compensation	948,300	710,162	
Provision for doubtful accounts	590,814	305,633	
Change in assets and liabilities:			
Accounts receivable	(12,410,361)	(3,871,403)	(
Inventory	(2,585,997)	1,144,159	(2,
Prepaid expenses and other current assets	(541,035)	(265,502)	
Accounts payable	644,186	2,422,905	
Accrued expenses and taxes withheld	5,535,613	250,908	1,
Deferred revenue	2,216,210	577,881	
Other	(465,609)	(404,572)	(
Net cash used by operations	(3,431,195)	(30,283,617)	(30,
CASH FLOWS FROM INVESTING ACTIVITIES			
Maturities (purchase) of short-term investments, net	(1,028,191)	3,677,230	(10,
Purchase of property and equipment	(4,920,879)	(4,564,549)	(2,
Purchase of radiation and transfer devices	(13,140,984)	(5,612,763)	
Net cash used by investing activities	(19,090,054)	(6,500,082)	(12,
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock	1,915,698	56,163,122	48,
Payments on capital lease obligations	(261,918)	(52,248)	
Net cash provided by financing activities	1,653,780	56,110,874	48,
Effect of exchange rate changes on cash	233,357	94,198	
Net (decrease) increase in cash and cash equivalents	(20,634,112)	19,421,373	4,
Cash and cash equivalents at beginning of period	26,512,398	7,091,025	2,
Cash and cash equivalents at end of period	$ 5,878,286	$ 26,512,398	$ 7,
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid for interest on capital lease obligations	$ 74,091	$ 17,004	$
Noncash investing and financing activities:			
Assets acquired under capital leases	105,000	661,000	

See accompanying notes.

NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. SIGNIFICANT ACCOUNTING POLICIES

Organization and Basis of Presentation

Novoste Corporation (the "Company") was incorporated on January 8, 1987 and remained dormant until May 22, 1992 (date of inception) at which time it was capitalized. The Company is a medical device company that is engaged in commercializing the Beta-Cath/TM/ System, an intraluminal beta radiation catheter delivery system designed to reduce restenosis subsequent to percutaneous transluminal coronary angioplasty. In the course of its development activities the Company has sustained operating losses through December 31, 2001.

During years prior to 1998 the Company was in the development stage. In 1998 the Company received CE mark approval to sell the Beta-Cath/TM/ System in Europe and recorded its first sale of commercial product in December 1998. In November 2000, the Company received Food and Drug Administration (FDA) approval to sell the Beta-Cath/TM/ System in the United States. To achieve profitable operations, the Company must successfully achieve market acceptance. The Company plans to finance the Company with revenues from product sales. The Company's ability to continue its operations is dependent upon successful market acceptance and achieving profitable operations.

The consolidated financial statements include the accounts of Novoste Corporation and its wholly-owned subsidiaries incorporated in The Netherlands, Belgium, Germany and France. Significant intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue Recognition

The Company earns revenue from sales of catheters and from license and lease agreements to use the radiation source trains and transfer devices included in the Beta-Cath(TM) System. Novoste uses distributors in countries where the distributors experience and knowledge of local radiation and medical device regulatory issues is considered beneficial by the Company's management. Under the distributor arrangements, there are 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 once the hospital has leased a Beta-Cath(TM) System and completed all licensing and other requirements to use the system. The Company recognizes revenue from sales of catheters to distributors at the time of shipment.

The Company retains ownership of the radiation source trains and transfer devices and enters into either a lease or license agreement with its customers.

Revenue recognition begins once an agreement has been executed, the system has been shipped, and all licensing and other requirements to use the system have been completed. The terms of the operating lease signed with customers located in the United States requires, as dictated by FDA regulatory approval, replacement and servicing of the radiation source train and transfer device at six-month intervals. No other post-sale obligations exist.

During 1999 and through the second quarter of 2000, all payments under license agreements were payable at the inception of the agreement. These agreements were accounted for as sales-type leases and, accordingly,

revenue and the related costs of sales were recognized upon shipment. Beginning in the third quarter of 2000, after the Company determined the estimated useful life of the system exceeded one year, license and lease agreements were determined to be operating leases and, accordingly, revenue has been recorded over the term of the related agreements and costs are recorded over an eighteen month estimated useful life.

Beginning in the fourth quarter of 2000 and during 2001, payments under license and lease arrangements are either due in full at the inception of the agreement or over the term of the agreement as catheters are purchased. Revenue for these arrangements has been recorded using the lower of revenue earned based on accrual catheters purchased or on a straight-line basis over the term of the related agreements. Costs are recorded over an eighteen month estimated useful life of the radiation source train and transfer device.

During 2001, 2000 and 1999, approximately $6,814,000, $365,000 and $713,000, respectively, of net sales related to the lease of radiation transfer devices.

Accounts Receivable

Accounts receivable at December 31, 2001 and 2000 includes receivables due from product sales and amounts due under lease arrangements to hospitals relating to radiation and transfer devices (see Radiation and Transfer Devices). The carrying amounts reported in the consolidated balance sheets for accounts receivable approximate their fair value.

The Company's distributor for the markets of Australia, New Zealand and China accounted for 20% of sales in 2000. There were no significant concentrations of credit risk in 2001. The Company performs periodic credit evaluations of its customer's financial condition and generally does not require collateral. Management records estimates of expected credit losses and returns of product sold. Bad debt expense for the years ended December 31, 2001, 2000 and 1999 amounted to $590,000, $311,000 and $0, respectively. For December 31, 2001, 2000 and 1999, uncollectible accounts written off totaled $22,886, $0 and $0, respectively.

Receivable from Officers

In October 2001, the Company adopted a split-dollar life insurance plan for all officers. The Company matches officer contributions to the plan. During 2001, the Company charged $180,000 to compensation expense for such contributions. In addition, the Company advanced the officers a total of $144,000 for related payroll taxes. This amount is reflected as a receivable

from officers on the balance sheet. In accordance with the plan agreement, if an officer leaves the Company for any reason, retires or in any way terminates or withdraws from the plan, then the life insurance company is obligated to repay the Company for the tax advances prior to settlement of the account with the officer. The advances are unsecured and are subject to the life insurance company's ability to repay the Company in the future.

Advertising Costs

All advertising costs are expensed as incurred. Approximately $1,350,000, $1,155,000 and $539,000 was charged to advertising expense for the years ended December 31, 2001, 2000 and 1999, respectively.

Basic and Diluted Loss Per Share

The basic and diluted loss per share is computed based on the weighted average number of common shares outstanding. Common equivalent shares of 3,506,144, 2,483,157 and 2,108,561 are not included in the per share calculations for 2001, 2000 and 1999, respectively where the effect of their inclusion would be antidilutive.

Cash Equivalents and Short-term Investments

The Company maintains cash equivalents and investments in several large well-capitalized financial institutions. The Company's investment policy does not allow investment in any debt securities rated less than "investment-grade" by national rating services. Cash equivalents are comprised of certain highly liquid investments with maturities of less than three months when purchased. In addition to cash equivalents, the Company has investments in commercial paper and certificates of deposit that are classified as short-term (mature in more than 90 days but less than one year). These investments are accounted for in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, Accounting for Certain Investments in Debt and Equity Securities ("SFAS 115").

Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. The Company has classified all investments as available for sale. Available for sale securities are carried at fair value, with the unrealized gains and losses reported in a separate component of shareholders' equity if significant. Realized gains and losses are included in investment income and are determined on a specific identification basis (Note 6).

Concentrations of Finance Risk

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

Foreign Currency Risk

International revenues from the Company's foreign direct sales and distributor sales comprised 7%, 74% and 100% of total revenues for the years ended December 31, 2001, 2000 and 1999, respectively. All foreign sales are denominated in Euros. The Company experienced an immaterial amount of transaction gains and losses in 2001 and 2000 when converting from local currencies into the respective functional currencies. The Company is also exposed to foreign exchange rate fluctuations as the financial results of its Dutch, Belgian, German and French subsidiaries are translated from Euros into U.S. dollars for reporting purposes during consolidation. As exchange rates vary from period to period, these results, when translated into U.S. dollars (the reporting currency), may vary from expectations and adversely impact overall expected profitability. The net effect of foreign exchange rate fluctuations during 2001, 2000, and 1999 are reflected in accumulated other comprehensive income on the consolidated statement of shareholders' equity.

Inventories

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

	December 31, 2001	December 31, 2000
Raw Materials..	$1,971,347	$ 777,819
Work in Process	811,406	218,958
Finished Goods.	963,680	254,910
Total.....	$3,746,433	$1,251,687

Property and Equipment

Property and equipment, including amounts under capital leases (Note 7), are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets ranging from three to seven years. Leasehold improvements are amortized over the remaining term of the underlying lease using the straight-line method. Repairs and maintenance are expensed as incurred.

Property and equipment is comprised of the following:

	December 31, 2001	December 31, 2000
Furniture and Fixtures.....	$ 1,358,180	$ 1,217,807

Office Equipment	4,759,623	3,632,468
Laboratory Equipment	732,818	570,719
Leasehold Improvements	2,131,813	1,585,553
Production Equipment	7,119,161	4,097,877
	16,101,595	11,104,424
Less: Accumulated Depreciation and Amortization	(6,214,884)	(3,826,690)
	$ 9,886,711	$ 7,277,734

Radiation and Transfer Devices

The Company retains ownership of the radiation source trains (RSTs) and transfer devices (TDs). During 1999, the Company was the lessor of RSTs and TDs under annual sales-type lease agreements expiring through December 2000. During the second quarter of 2000, the Company determined that based upon experience, testing and discussions with the FDA the estimated useful life of RSTs and TDs would exceed one year. Accordingly, at that time the Company reclassified these assets from inventory to a long-term asset named radiation and transfer devices. Depreciation of the costs of these assets is included in cost of sales and is recognized over their estimated useful lives (currently estimated at 18 months) using the straight-line method. Depreciation begins once the Beta-Cath/TM/ System is placed into service. Concurrent with the change in estimated life, the RST and TD annual agreements to license the use of the radiation and transfer devices are classified by the Company as operating leases.

At December 31, 2001, equipment of approximately $8,310,000, net of accumulated depreciation of approximately $5,219,000 was leased under operating leases. Approximately $5,224,000 of radiation and transfer devices were available for lease at December 31, 2001. At December 31, 2001, lease payments receivable under these operating leases approximated $1,032,000 and are recorded in accounts receivable.

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

	December 31, 2001	December 31, 2000
Radiation and Transfer Devices	$18,753,747	$5,612,763
Less: Accumulated Depreciation	5,219,391	131,815
	$13,534,356	$5,480,948

Long-Lived Assets

In accordance with Statement of Financial Accounting Standards No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of ("SFAS 121"), long-lived assets are

reviewed for impairment whenever events indicate that their carrying amount may not be recoverable. In such reviews, estimated undiscounted future cash flows associated with these assets are compared with their carrying value to determine if a write-down to fair value (normally measured by discounting estimated future cash flows) is required.

Research and Development and Patent Costs

All research and development costs are charged to operations as incurred. Legal fees and other direct costs incurred in obtaining and protecting patents are expensed as incurred.

Shipping Costs

All shipping costs incurred by the Company are classified as Cost of Sales.

Stock Based Compensation

SFAS No. 123, Accounting for Stock-Based Compensation ("SFAS 123") sets forth accounting and reporting standards for stock-based employee compensation plans (Note 9). As permitted by SFAS 123, the Company accounts for stock options grants in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25") and related interpretations. Under APB 25 no compensation expense is recognized for stock option grants to employees for which the terms are fixed. The Company 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.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force (EITF) 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 earns those options.

New Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 133, Accounting and Reporting for Derivative Instruments. SFAS 133 establishes accounting and reporting standards for derivative and hedging activities. SFAS 133, as amended by SFAS 137 and SFAS 138, was adopted by the Company on January 1, 2001. The adoption of these statements did not have a material impact on the Company's financial statements.

In June 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143 addresses accounting and reporting for obligations associated with the retirement of tangible long-lived assets. SFAS 143 is effective for fiscal years beginning after June 15, 2002. The Company is currently assessing the impact of SFAS 143 on its financial statements.

In June 2001, the FASB issued SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. Under the new rules, goodwill and indefinite lived intangible assets are no longer amortized but are renewed annually for impairment, or move frequently if impairment indicators arise. The adoption of this standard did not have a material impact on the Company's financial statements.

In July 2001, the FASB issued SFAS No. 144, Impairment or Disposal of Long-Lived Assets, which is effective for fiscal years beginning after December 15, 2001. The provisions of this statement provide a single accounting model for impairment of long-lived assets. The Company does not expect that the adoption of SFAS 144 will have a material impact on its financial statements.

Reclassifications

Certain amounts have been reclassified in prior year statements to conform to current year presentation.

2. CONSULTING AGREEMENTS

The Company has agreements with certain physicians, various consultants and others with terms ranging from one to five years. Substantially all of these agreements provide for stock or stock option grants on the agreement dates. Shares issued under these agreements are generally valued at fair value on the date of grant and include certain registration rights. Stock option grants under these agreements are measured in accordance with EITF 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services. During 2001, 2000, and 1999 approximately, $20,000, $399,000 and $374,000, respectively, was charged to operations as amortization of deferred compensation under these agreements in accordance with their vesting terms.

3. COMMITMENTS AND CONCENTRATIONS OF SUPPLIERS

The Company is committed under operating leases for its facility and various office equipment. Rent expense was approximately $956,000, $707,000 and $607,000 for 2001, 2000, and 1999, respectively. The total future minimum rental payments are as follows:

2002	$ 712,800
2003	556,100
2004	24,750
	$1,293,650

The Company has entered into a license agreement with a physician pursuant to which he is entitled to receive a royalty on the net sales of the Beta-Cath(TM)System (excluding consideration paid for the radioactive isotope), subject to a maximum payment of $5,000,000. Royalty fees to the physician

aggregated $632,300, $63,200 and $11,250 in 2001, 2000 and 1999 and have been expensed in cost of sales.

On January 30, 1996, the Company entered into a license agreement whereby Emory University assigned its claim to certain technology to the Company for royalties based on net sales (as defined in the agreement) of products derived from such technology, subject to certain minimum royalties. The royalty agreement term is consistent with the life of the related patent and applies to assignments of the patent technology to a third party. Royalty fees to Emory University aggregated $1,441,800, $146,050 and $36,330 in 2001, 2000 and 1999 and have been expensed in cost of sales.

During 2000, and 1999, the Company obtained all of its requirements of radiation source materials (totaling $1,487,000 and $1,270,000, respectively) pursuant to an agreement, as amended (the "Supply Agreement"), with a single German supplier, Bebig Isotopentechnik und Umweltdiagnostik GmbH. In 2001, the Company purchased radiation source materials from two suppliers, Bebig Isotopentechnik und Umweltdiagnostik GmbH and AEA Technologies QSA, GmbH, totalling $2,438,000 and $1,115,000 respectively. At December 31, 2001, the Company had commitments to purchase approximately $7,185,000 of various inventory components for the Beta-Cath/TM/ System.

On October 14, 1999, the Company signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH for a second source of radioisotope supply and for the development of a smaller

diameter source. This agreement provides for the construction of a production line beginning October 1999 with expected completion in mid-2002. The cost of this production line is estimated at $4,000,000 and will be paid by the Company as construction progresses. At December 31, 2001, the Company had a commitment remaining under this contract of approximately $110,000.

Significant proportions of key components and processes relating to the Company's products are purchased from single sources due to technology, availability, price, quality, and other considerations. Key components and processes currently obtained from single sources include isotopes, protective tubing for catheters, proprietary connectors, and certain plastics used in the design and manufacture of the transfer device. In the event a supply of a key single-sourced material or component was delayed or curtailed, the Company's ability to produce the related product in a timely manner could be adversely affected. The Company attempts to mitigate these risks by working closely with key suppliers regarding the Company's product needs and the maintenance of strategic inventory levels.

The Company maintains termination agreements with certain executives providing for severance pay and other related benefits upon separation from the Company under a change of control.

The Company is subject to legal claims and assertions in the ordinary course of business. At December 31, 2001, the Company is not aware of any such assertions that are material to the Company's financial statements.

4. LINE OF CREDIT

In August 2001, the Company entered into a $10 million revolving line of credit with a financial institution (lender) that matures in August 2002. At December 31, 2001, there were no outstanding borrowings under this agreement. The Company may borrow an amount not to exceed the borrowing base as defined in the loan agreement. Interest is payable on the first of each month calculated on the outstanding balance and accrues at a rate of the bank's prime rate plus 1%. At such time that the Company sustains three consecutive months of profitability, the rate decreases to the prime rate. The Company granted the lender first priority security interest in substantially all assets of the Company. Additionally, the loan agreement contains certain financial and non-financial covenants.

The Company also has letters of credit available under the revolving line of credit. The lender will issue or have issued letters of credit for the Company's account subject to certain limitations; however they may not exceed $500,000.

5. INCOME TAXES

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the corresponding amounts used for income tax purposes. Significant components of the Company's deferred income tax assets for federal and state income taxes are as follows:

	December 31, 2001	December 31, 2000
Deferred Income Tax Assets:		
Net operating loss carryforwards	$ 48,334,941	$ 48,342,183
R&D tax credit carryforwards	1,481,225	1,881,913
Provision for doubtful accounts	57,000	118,298
Deferred revenue	--	220,710
Other	--	237,991
Accruals/reserves	1,436,791	--
Property and Equipment	935,714	--
Deferred compensation	360,352	--
	52,606,023	50,801,095
Valuation allowance for Deferred Income Tax assets	(52,606,023)	(50,801,095)
Net Deferred Income Tax Assets	$ --	$ --

At December 31, 2001 and 2000, a valuation allowance has been recognized to reduce the net deferred tax assets to zero due to uncertainties with respect to the Company's ability to generate taxable income in the future sufficient to realize the benefit of deferred income tax assets. No income taxes were paid during 2001, 2000, or 1999. The Company has approximately $103.3 million of net operating losses for U.S. federal income tax purposes available to offset

future taxable income. Such losses expire in 2007 through 2021 and may be subject to annual limitations on usage due to changes in ownership. Net operating loss carry forwards aggregating approximately $13.4 million representing cumulative exercises of non-qualified stock options will result in a credit to contributed capital when recognized. In addition the company has approximately $10.5 million of foreign net operating losses related to its European subsidiaries. The activity in the valuation allowance includes the tax effect of these non-qualified stock options. Additionally, the Company has approximately $1.5 million in research and development tax credits that expire in 2008 through 2021 unless utilized earlier.

A reconciliation of the provision for income taxes to the federal statutory rate is presented below for the years ended December 31:

	2001	2000	1999
Tax benefit at statutory	(1,737,006)	(11,244,981)	$(10,512,872)
State tax, net of federal benefit	(203,679)	(1,322,939)	(1,236,809)
R&D tax credit	(441,262)	(501,561)	(361,897)
Other	577,019	61,027	37,777
Valuation allowance for deferred income tax	1,804,928	13,008,454	12,073,801
	$ --	$ --	$ --

6. INVESTMENTS

At December 31, 2001 and 2000, short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days from the date of acquisition. All available-for-sale securities mature within one year. The Company has invested primarily in commercial paper and U.S. corporate notes, all of which have a minimum investment rating of A, in addition to government agency notes and certificates of

deposit. The Company had insignificant realized gains or losses from the sale of investments for the years ended December 31, 2001, 2000 and 1999. At December 31, 2001 and 2000, cost of the short-term investments approximated fair value.

7. CAPITAL LEASE OBLIGATIONS

The Company leases computers and equipment under capital leases with initial or remaining terms in excess of one year or more. During the year ended December 31, 2001, lease payments under capital leases were $296,255. Amortization of assets recorded under capital leases is included in depreciation expense.

Future minimum lease payments under capital leases are as follows:

2002	$303,399
2003	192,407
2004	5,333
	$501,139
Less amounts representing interest	48,792
	$452,347

8. RESTRUCTURING CHARGES AND OTHER EXPENSE

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

During 2001, the Company contributed $440,000 for an 8% ownership interest in an equity method investment. This amount was subsequently expensed as a result of the impairment of that investment.

9. SHAREHOLDERS' EQUITY

Shareholder Rights Plan

On October 25, 1996, the Company's Board of Directors declared a dividend of one Right for each share of Common Stock held of record at the close of business on November 25, 1996. The Rights are generally not exercisable until 10 days after an announcement by the Company that a person has acquired at least 15% of the Company's Common Stock. Each Right, should it become exercisable, will entitle the owner to buy 1 1/100th of a share of new Series A participating preferred stock at an exercise price of $85. The Rights, which do not have any voting rights, may be redeemed by the Company at a price of $.01 per Right at any time prior to a person's or group's acquisition of 15% or more of the Company's Common Stock.

In the event the Rights become exercisable as a result of the acquisition of at least 15% of the Company's Common Stock, each Right will entitle the owner, other than the acquiring person, to buy at the Rights' then current exercise price a number of shares of Common Stock with a market value equal to twice the exercise price. In addition, unless the acquiring person owns more than 50% of the outstanding shares of Common Stock, the Board of Directors may elect to exchange all outstanding Rights (other than those owned by such acquiring person or affiliates thereof) at an exchange ratio of one share of Common Stock per Right. The Rights expire on November 25, 2006 unless they are earlier exercised, redeemed, or exchanged. As a result of the adoption of the Shareholders' Rights Plan, 1,000,000 shares of authorized preferred stock have been reserved and designated as Series A Participating Preferred Stock.

Stock Option Plans and Stock Grant

The Company's Board of Directors adopted in May 1992, the Novoste Corporation Stock Option Plan (the "Plan") under which options designated as either incentive or non-qualified stock options may be issued to employees, officers, directors, consultants and independent contractors of the Company or any parent, subsidiary or affiliate of the Company. Options granted under the Plan are at prices not less than the fair market value on the date of grant and may be exercised for a period of ten years from the date of grant. Options granted under the Plan have vesting periods ranging from immediately to four years. The Plan includes a provision for options to accelerate and become immediately and fully exercisable upon a 50% or more change in control as defined in the Amended and Restated Stock Option Plan. In 2001, this plan was terminated and replaced with the 2001 Stock Plan. In August 1996 the Stock Option and Compensation Committee of the Board of Directors of the Company adopted a Non-Employee Director Stock Option Plan (the "Director Plan"). In 2001, this plan was terminated and replaced with the 2001 Stock Plan.

During April 2001, the 2001 Stock Plan (the "2001 Plan") was adopted by the Company's Board of Directors and on June 14, 2001, the 2001 Plan was approved by the Company's Shareholders. Any employee, officer, consultant, independent contractor or director is eligible to participate in the 2001 Plan. The Novoste 2001 Stock Plan permits the granting of both incentive and non-qualified stock options, stock appreciation rights, restricted stock, performance awards and common stock. Options granted under the 2001 Plan are at prices not less than the fair market value on the date of grant and may be exercised for a period of ten years from the date of grant. Options granted under the 2001 Plan have vesting periods ranging from immediately to four years. The 2001 Plan includes a provision for options to accelerate and become immediately and fully exercisable upon a 50% or more change in controls as defined in the Amended and Restated Stock Options Plan.

Activity under the above-described three plans is summarized as follows:

	Number of Shares	Price Per Share	Weighted Average Price
Outstanding at December 31 1998.	2,309,238	$ .250-29.625	$11.60
Options granted.....	715,800	11.000-28.375	19.42
Options exercised.....	(901,815)	.250-17.250	0.98
Options forfeited.....	(53,516)	3.200-28.250	16.48
Outstanding at December 31, 1999	2,069,707	1.000-29.625	18.30
Options granted.....	978,444	20.750-49.250	28.83
Options exercised.....	(426,544)	1.000-29.630	16.75
Options forfeited	(169,166)	9.750-28.250	19.50
Outstanding at December 31, 2000	2,452,441	1.000-49.250	22.69
Options granted.....	1,425,300	6.65-34.750	9.52
Options exercised.....	(117,188)	3.20-27.000	10.75
Options forfeited.....	(260,045)	6.65-49.250	25.11
Outstanding at December 31, 2001	3,500,558	$ 1.000-49.250	$17.53

Exercisable at December 31, 2001 1,434,761 $ 1.000-49.250 $18.44

NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

In December 31, 2001 the Company has 3,755,491 shares of common stock reserved for issuances under these employee and director stock option agreements and 43,733 shares of common stock reserved for issue under the Employee Stock Purchase Plan (Note 10).

The following table summarizes information concerning currently outstanding and exercisable options:

Options Outstanding				Options Exercisable	
Range Of Exercise Prices	Number Of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price Of Options Outstanding	Number Exercisable	Weighted Average Exercise Price
$ 1.00-$ 5.00	45,650	1.47	$ 2.96	45,650	$ 2.96
5.01- 7.00	991,250	9.72	6.65	247,625	6.65
7.01- 10.50	61,900	9.96	8.24	20,000	7.63
10.51- 13.38	344,134	7.06	11.72	219,949	11.79
13.39- 21.94	555,200	7.51	17.12	212,925	18.31
21.95- 22.50	441,275	8.78	22.50	120,205	22.50
22.51- 24.69	508,700	6.58	23.96	367,625	24.00
24.70- 49.25	552,449	7.63	33.45	200,782	32.38
	3,500,558	8.10	17.53	1,434,761	18.44

During the period October 1998 to February 1999, options to purchase 200,000 shares were granted at prices per share ranging from $11.75 to $28.00 per share. These grants were subject to shareholder approval in May 1999. When approval was obtained, the market price per share exceeded the exercise price, and the Company incurred compensation of $1,792,500, which will be expensed over the four-year vesting period of these options: $415,000, $431,000 and $532,000 was expensed in 2001, 2000 and 1999, respectively). Approximately 37,500 of these options awarded to a former officer of the Company were forfeited during 2000.

In May 1996, the Company amended an option to purchase 100,000 shares of Common Stock at $3.20 per share of which options for 75,000 shares had not yet become exercisable. As amended, options to purchase such 75,000 shares became exercisable at the annual rate of 25,000 shares beginning May 20, 1997, subject to acceleration upon the achievement of three specified milestones at the rate of 25,000 shares per milestone. The Company recorded total non-cash compensation expense of $810,000 ratably over the three-year period ending May 19, 1999. Approximately $101,250 was expensed in 1999 relating to these options.

In April 2001, options to purchase 101,000 shares were granted at $14.71 per share. These grants were subject to shareholder approval in June 2001. When approval was obtained, the market price per share exceeded the exercise price, and the Company incurred compensation of $839,000, which will be expensed over the vesting period of these options. The vesting period allowed for one-quarter vesting of the options on the date of grant and the remainder to be vested one-quarter over the next three grant date anniversaries. Approximately $344,800 was expensed in 2001 relating to these options.

Pro forma information regarding net loss and net loss per share is required by SFAS 123, and has been determined as if the Company had accounted for its employee and director stock options under the fair value method of SFAS 123. The fair value for options was estimated at the date of grant using the Black-Scholes option-pricing model. The following weighted-average assumptions were used for 2001, 2000 and 1999: risk-free interest rates of 4.22%, 5.66% and 5.20%, respectively; no dividend yields; volatility factor of the expected market price of the Company's common stock of 1.29, 1.29 and 0.577, in 2001, 2000 and 1999, respectively; and a weighted-average expected life of the option of five years for 2001 and 2000 and six years for 1999.

Option valuation models used under SFAS 123 were developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require input of highly subjective assumptions including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information follows:

	Year Ended December 31,		
	2001	2000	1999
Pro forma net loss	$17,658,365	$41,014,516	$37,131,898
Pro forma net loss per share	(1.09)	(2.64)	(2.76)
Weighted average fair value of options granted	10.07	15.98	11.30
Weighted average fair value of non-vested restricted stock	23.02	18.86	17.30

During 2001, 2000, and 1999, the Company has granted a total of 56,450 shares of restricted Common Stock from the Plan to consultants and certain officers of the Company. Of these restricted shares, 7,500 were cancelled during 2000. In October 2001, the Company accelerated the vesting of 39,000 shares of restricted stock previously issued to an officer. The Company

recognized approximately $190,000 in expense associated with the accelerated vesting. As of December 31, 2001, 43,363 of these restricted shares have vested. The remaining 5,586 shares will vest over the three or four year vesting period from the date of grant provided that the consultant continues to provide services and the officer is still employed by the Company. Holders of these shares have voting rights once the shares vest. Based on the quoted market value per share at the grant dates, the Company incurred compensation of $434,000, $279,000 and $231,000 in 2001, 2000, and 1999, respectively. The value of the remaining shares awarded totaled $138,000 at December 31, 2001 and has been recorded as unearned compensation in the statement of shareholders' equity. Such unearned compensation is being amortized to compensation expense over the vesting periods of the awards.

10. EMPLOYEE BENEFIT PLANS

The Company has adopted a Defined Contribution 401(k) Plan in which all employees who are at least 21 years of age are eligible to participate. Contributions of up to 15% of compensation to the 401(k) Plan may be made by employees through salary withholdings. Company matching contributions are discretionary. In 2001, 2000, and 1999 the Company matched 33 1/3% of the first 6% of employee contributions, aggregating $239,000, $124,000 and $90,000, respectively.

Effective July 1, 2000, the Company adopted an Employee Stock Purchase Plan ("Plan"), which makes available up to 100,000 shares of Common Stock of the Company to be sold to eligible employees under the Plan. The purchase price of each share of Common Stock sold pursuant to this Plan shall be the lesser of 85% of the Fair Market Value of such share on the first day of the purchase period or 85% of the Fair Market Value of such share on the last day of the purchase period. As of December 31, 2001, 56,267 shares have been purchased under the Plan.

11. SEGMENT INFORMATION

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

The Company's net sales, loss from operations and long-lived assets by geographic area are as follows:

Net Sales	United States	Europe	Rest of World	Consolidated
2001.....	$64,696,793	$4,576,114	$635,389	$69,908,296
2000.....	1,816,250	$4,224,776	488,555	6,529,581

1999.....	18,000	1,510,394	295,000	1,823,394

Income (Loss) from operations	United States	Europe	Rest of World	Consolidated
2001.....	$ 2,953,210	$(7,524,276)	$(537,775)	$ (5,108,841)
2000.....	(27,683,138)	$(5,235,572)	(154,763)	(33,073,473)
1999.....	(26,489,952)	(4,393,224)	(37,036)	(30,920,212)

Long-lived assets	United States	Europe	Rest of World	Consolidated
2001.....	$23,400,897	$1,047,506	--	$24,448,403
2000.....	12,512,353	$1,188,756	--	13,701,109
1999.....	3,669,007	575,176	--	4,244,183

The Company's distributor for the markets of Australia, New Zealand and China accounted for 20% of net sales in 2000 and 14% in 1999. In 2001, net sales for the Company's distributors outside the U.S. market were less than one percent of net sales. At December 31, 2001 and 2000, the Company's net assets outside of the United States, consisting principally of cash and cash equivalents, accounts receivable, inventory and office equipment, were approximately $6,192,000 and $6,101,000, respectively.

12. SUBSEQUENT EVENT

In January 2002, the company incurred a compensation charge in the amount of $330,000 in connection with a severance payout upon the resignation of an officer of the Company. The related compensation was awarded through a combination of cash and the accelerated vesting of options.

13. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Fiscal 2001	First Quarter Ended March 31	Second Quarter Ended June 30	Third Quarter Ended September 30	Fourth Quarter Ended December 31
Net sales and revenue.....	$ 9,290,629	$ 17,290,707	$ 20,916,638	$ 22,410,322
Cost of sales.....	3,744,504	5,725,840	5,118,949	4,575,143
Gross Margin.....	5,546,125	11,564,867	15,797,689	17,835,179
Income (loss) from operations	(7,246,946)	(3,884,953)	1,612,921	2,315,137
Net income (loss).....	(6,628,567)	(3,296,606)	2,086,241	2,730,091
Net income (loss) per share..	(0.41)	(0.20)	0.13	0.17

Fiscal 2000	First Quarter Ended March 31	Second Quarter Ended June 30	Third Quarter Ended September 30	Fourth Quarter Ended December 31
Net sales and revenue.....	846,046	1,197,647	1,301,771	3,184,117
Cost of sales.....	753,380	770,013	833,390	1,900,819
Gross Margin.....	92,666	427,634	468,381	1,283,298

Loss from operations.....	(7,799,879)	(8,178,103)	(9,807,332)	(11,033,625)
Net loss.....	(7,198,942)	(7,129,133)	(8,704,782)	(10,040,616)
Net loss per share.....	(0.50)	(0.45)	(0.54)	(0.63)

The Company recorded a restructuring charge and other expense in the amount of $1.2 million during the fourth quarter ended December 31, 2001.

SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 29, 2002.

NOVOSTE CORPORATION

By: /s/ THOMAS D. WELDON
Thomas D. Weldon
Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on March 29, 2002.

/s/ THOMAS D. WELDON Thomas D. Weldon	Chairman and Chief Executive Officer (Principal Executive Officer)
/s/ EDWIN B. CORDELL, JR. Edwin B. Cordell, Jr.	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ WILLIAM A. HAWKINS William A. Hawkins	Director
/s/ DONALD C. HARRISON Donald C. Harrison, M.D.	Director
/s/ J. STEPHEN HOLMES J. Stephen Holmes	Director
/s/ CHARLES E. LARSEN Charles E. Larsen	Director
/s/ STEPHEN I. SHAPIRO Stephen I. Shapiro	Director
/s/ NORMAN R. WELDON Norman R. Weldon, PhD.	Director

/s/ WILLIAM E. WHITMER

William E. Whitmer Director

INDEX TO EXHIBITS

Exhibit Numbers	Description
3.1	Articles of Incorporation of Registrant, as amended. (1)
3.2	Form of Amended and Restated Articles of Incorporation of Registrant filed on May 28, 1
3.2(a)	Copy of First Amendment to Amended and Restated Articles of Incorporation of Novoste Corporation filed with the Department of State of the State of Florida on November 1, 1
3.3(a)	Copy of Amended and Restated By-Laws of Registrant adopted December 20, 1996. (3)
4.1	Form of Specimen Common Stock Certificate of Registrant. (1)
4.2	Registration Rights Agreement, dated July 28, 1995, by and among Registrant, Norman R. Weldon, Thomas D. Weldon, Charles E. Larsen, the Hillman Investors (as defined therein) Moseley Partners-III, L.P. and Advanced Technology Ventures IV, L.P. (1)
4.17(a)	Amended and Restated Rights Agreement, dated as of July 29, 1999, between Novoste Corporation and American Stock Transfer & Trust Company, which includes as Exhibit B th the Form of Right Certificate. (2)
4.17(b)	Amended and Restated Summary of Rights to Purchase Preferred Shares of Novoste Corporation. (2)
4.20	Registration Rights Agreement dated as of March 28, 2000 by and among Novoste Corporati and the investors listed on the signature pages thereto. (12)
*10.1	Copy of Stock Option Plan of Registrant, as amended. (3)
H10.2	License Agreement, dated January 30, 1996, between Emory University and Registrant. (1)
H10.4	License Agreement, dated January 31, 1996, between Spencer B. King III, M.D. and Registrant. (1)
H10.5	Restenosis Therapy Project Development and Supply Agreement, dated November 28, 1994, w Registrant, relating to the supply of radioactive beta isotopes. (1)
H10.6	Option to Purchase Assets Agreement dated August 22, 1995, with Registrant relating to purchase of assets of Registrant's supplier of radioactive beta isotopes. (1)
H10.10	Frame Agreement with Bebig Isotopentechnik und Umweltdiagnostik GmbH regarding purchase and investment grant. (3)
*10.12	Copy of Non-Employee Director Stock Option Plan. (3)
H10.13	Memorandum of Understanding between Registrant and Bebig Isotopentechnik und Umweltdiagnostik GmbH regarding purchases and investment grant dated April 23, 1997. (4

10.14	Employment Agreement with William A. Hawkins III. (5)
10.16	Restricted Stock Award Agreement with William A. Hawkins III. (5)
10.17	Non-Incentive Stock Option Agreement with William A. Hawkins III. (5)
H10.18	Amendment to Framework Agreement and Security Agreement with Bebig GmbH. (5)
10.19	Lease, dated October 23, 1998, between Weeks Realty, L.P. and Registrant. (6)
H10.20	Manufacturing and Supply Agreement dated April 21, 1998 between Registrant and SeaMED Corporation. (7)
#10.20a	Manufacturing and Supply Agreement dated September 1, 1999 between Registrant and SeaME a Plexus Company. (11)
*10.22	Restricted Stock Award dated July 1, 1999 between Novoste Corporation and William A. Hawkins. (9)

Exhibit Numbers	Description
H10.25	Development and Manufacturing Agreement between AEA Technology -QSA GmbH and Novoste Corporation. (10)
H10.27	Amendment to the Framework Agreement and Security Agreement (NOV 34) between Registrant and Bebig Isotopentechnik und Umweltdiagnostik GmbH. (11)
10.29	Amendment to the Framework and Security Agreement (NOV 34) between Registrant and Bebig Isotopentechnik und Umweltdiagnostik GmbH. (14)
10.30	Loan and Security Agreement dated August 1, 2001 between Silicon Valley Bank and Novoste Corporation. (13)
10.31	Negative Pledge Agreement dated August 1, 2001 between Silicon Valley Bank and Novoste Corporation. (13)
10.32	Form of change of control agreement executed between Novoste Corporation and Executive officers. (13)
*10.33	Executive Deferred Income Plan.
23.1	Consent of Ernst & Young LLP, Independent Auditors

H Portions have been omitted and filed separately with the Securities and Exchange Commission pursuant to an order granting confidential treatment.

(1) Filed as same numbered Exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-4988).

(2) Filed as same numbered Exhibit to the Registrant's Report on Form 8-A/A filed on August 3, 1999.

(3) Filed as Exhibit A to the Registrant's Proxy Statement for its 2001 Annual

Meeting of Stockholders filed on April 30, 2001.

(4) Filed as same numbered Exhibit to the Registrant's Registration Statement on Form S-3 (File No. 333-38573).

(5) Filed as same numbered Exhibit to the Registrant's Report on Form 10-Q filed on August 11, 1998.

(6) Filed as same numbered Exhibit to the Registrant's Report on Form 10-Q filed on November 9, 1998.

(7) Filed as same numbered Exhibit to the Registrant's Report on Form 8-K filed on January 27,1999.

(8) Filed as same numbered Exhibit to the Registrant's Registration Statement on Form S-3 (File No. 333-72073).

(9) Filed as same numbered Exhibit to the Registrant's Report on Form 10-Q filed on August 11, 1999.

(10) Filed as same numbered Exhibit to the Registrant's Report on Form 10-Q filed on November 5, 1999.

(11) Filed as same numbered Exhibit to the Registrant's Report on Form 10-Q filed May 15, 2000.

(12) Filed as same numbered Exhibit to the Registrant's Report on Form 8-K filed April 6, 2000

(13) Filed as same numbered Exhibit to the Registrant's Report on Form 10-Q filed November 14, 2001.

(14) Filed as same numbered Exhibit to the Registrant's Report on Form 10-Q filed August 14, 2001.

* Constitutes a compensatory plan, contract or arrangement.