NOVOSTE CORPORATION
2002 Annual Report

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Novoste Corp
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Dear Shareholders:

Fiscal 2002 was a challenging year for Novoste. We have come through these challenges a better and more focused company. Our people have performed superbly. Our future is based upon the promising clinical trials we are conducting for treatment of failed vascular access grafts and peripheral artery disease. And, we expect our cardiology business to be profitable going forward.

Al Novak
President and Chief Executive Officer

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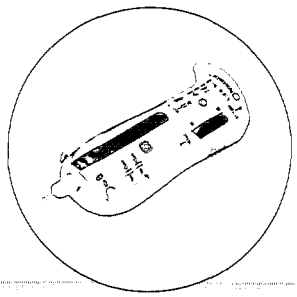
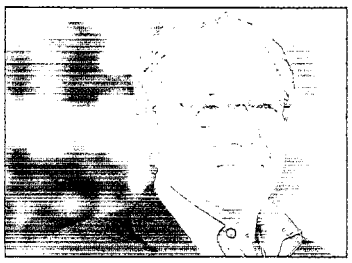


Novoste Corporation, based in Atlanta, Georgia, develops advanced medical treatments for coronary and vascular diseases and is the worldwide leader in vascular brachytherapy – radiation therapy delivered inside a blood vessel to prevent it from re-closing (restenosis) following balloon angioplasty and other catheter-based interventional procedures. The Novoste™ Beta-Cath™ System is commercially available in the United States, as well as in the European Union and several other countries. The Beta-Cath™ System is primarily used to treat patients suffering from "in-stent" restenosis, a condition in which coronary stents become blocked with new tissue growth. It is estimated that approximately 150,000 patients in the U.S. need treatment for this condition annually. The Company has also initiated clinical trials to investigate the role of vascular brachytherapy to treat peripheral artery disease and arterial-venous dialysis graft stenosis, markets that could exceed the coronary market opportunity.



Al Novak

If I could choose one word that best describes Novoste and our employees, it would be *resilient.*

I believe that after reading my comments regarding the Company's performance in 2002 and our expectations for 2003, you will understand why. Your employees have acted remarkably, given the setbacks that they faced in fiscal 2002.

Frankly, 2002 was a tough, yet insightful, year. Novoste's growth rate was challenged by a voluntary recall of the smaller-sized and more clinically significant catheter product, the ß-Rail™ 3.5F catheter, in August 2002. Despite this major setback, we were able to generate sales of $69 million compared to sales of $69.9 million for fiscal 2001. Let's not forget that in fiscal 2000, sales were just $6.5 million. For fiscal 2002, we reported a $13 million net loss, or loss of $0.80 per share on shares outstanding of 16.3 million compared to a net loss in 2001 of $5.1 million, or $0.32 per-share loss on shares outstanding of 16.2 million. About 53% of that loss, $6.9 million, can be attributed to the write-down of our Beta-Cath™ 5F System assets during the second quarter as a result of the introduction of our ß-Rail™ 3.5F catheters. This was followed, on August 19, by

our voluntary recall, which caused us to have to re-introduce the Beta-Cath™ 5F catheters. Despite all this, and in the face of increasing competition, our sales force and marketing people did a superb job of managing this difficult process and maintaining our position as worldwide leader in the vascular brachytherapy market.

Truly, Novoste employees demonstrated how resilient they really are. Rather than reeling from our voluntary 3.5F catheter recall, they continued to maintain the viability and efficacy of our 5F system while we improved the 3.5F system. Additionally, with the help of our highly skilled R&D team and with the cooperation of the FDA, we were able to receive regulatory approval to re-introduce the 3.5F system to the market in just 98 days. So, despite the tremendous challenges we faced, the Company was able to maintain revenue levels from 2001 to 2002 because of Novoste employees' strength and sacrifice. And, they were able to resolve the recall, while helping the Company end the year in a strong cash position of more than $33 million.

The successful re-launch of the 3.5F catheters in January 2003 and the 95% penetration rate of available 3.5F sites we achieved in the following two months are nothing short of remarkable. In addition, our first quarter 2003 revenue levels clearly indicate that we are well-positioned for improved financial performance for the remainder of the year. To that end, our goals for the year are threefold: concentrate on our core cardiology business; improve our financial performance; and accelerate enrollment in our BRAVO (Beta Radiation for treatment of Arterial-Venous graft Outflow) and MOBILE (MOre patency with Beta In the Lower Extremity) trials to enable us to realize revenue from one or both of these areas in fiscal 2004.

Concentrate on our core cardiology business

Since we introduced the Beta-Cath™ System, our coronary vascular brachytherapy (VBT) treatment device, in Europe in 1999 and the United States in 2000, about 60,000 patients have been treated with the system. Now that we have become the worldwide leader in coronary VBT, one of our key goals this year is to concentrate on that core business and increase utilization in our current accounts.

While coronary stents have become one of the more successful options for treating stenosis, a narrowing of a coronary artery after a revascularization procedure, vascular brachytherapy has emerged as the standard of care for treating in-stent restenosis (ISR). In fact, VBT is the only proven, effective therapy for treatment of ISR. Based on analyst estimates, physicians' opinions and trial data, we believe about one million stent procedures will be performed in 2003. Of those million procedures, we would expect about 150,000 to restenose, thereby forming the basis of our opportunity in the coronaries.

We believe even as drug eluting stents (DES) enter the marketplace, VBT will continue to successfully treat stent failures. Again, based on informed sources, our view is that DES would impact our business in the second half of this year, penetrating perhaps, 40% of the total bare stent procedures, depending upon when they are introduced. We view the failure rate to be about 7% in DES clinical trials and 13% in bare metal stents, and would expect the DES failure rate to be higher in clinical practice.

There is no current scientific data to indicate success or failure of DES in treating in-stent restenosis. In many clinical situations, it would not be feasible to use DES even if it proved to be efficacious. Many

of our physician customers involved in drug eluting stent trials have told us that when those stents fail, they will rely on VBT for effective treatment.

Furthermore, we do not directly compete against stents. Instead, our competition comes from companies who have VBT technology that treat in-stent restenosis, namely Guidant Corporation. In the coming months as drug eluting stents penetrate the bare metal stent market, and as bare metal stent manufacturers, including Guidant and others, vie for market share, I firmly believe their attention necessarily will shift toward maintaining their position in the stent market, and away from coronary VBT.

At the same time, we intend to enhance our Beta-Cath™ System, making it even more convenient for our physician customers to use. For instance, we have launched a 60mm device to treat long, in-stent restenosis lesions and to allow non-cath lab personnel to remain outside the sterile field. Also, we will continue to explore ways to improve our systems and processes, such as extending the battery life in our transfer devices, furthering our ability to provide better customer service and achieve operating efficiencies in our own business.

The dynamics in the VBT market and our own ability to compete effectively with a significantly larger player in Guidant Corporation, combined with improvements in our product offering, are the foundations of why we believe that Novoste will continue to lead the coronary VBT market.

Improve our financial performance

Sadly, in January 2003 we reduced our workforce by about 12% to bring our operating expenses in line with market opportunity, which, in addition to our core cardiology business, now lies in two areas: arterial-venous graft stenosis and femoral-popliteal disease. Our goal is to generate revenues from one or both of those businesses during 2004. If we can achieve this goal, I am certain we will have done the things that will allow us to succeed in the future.

Given the changes that are occurring in the cardiology market, we determined it was essential for us to be in a position that we could be profitable at current sales levels. This meant critically reviewing non-value-added activities, pruning our R&D projects and scaling back our headcount. We are confident that we will see the results of these actions translated into profitability in the first quarter of 2003, as well as generating positive cash flow. We intend to continue to be disciplined in the financial management of Novoste while investing in both R&D and the clinical trials necessary for us to build a strong company with a future based upon our leadership in vascular brachytherapy.

Positioned for growth

The BRAVO trial is directed to the more than 300,000 patients in the U.S. who require dialysis almost every other day. Half of the arterial-venous (A-V) access grafts occlude within one year and most occlude within two years of placement. Once they occlude, they require intervention to re-open them almost every three months, at a cost to our healthcare system of over a billion dollars per year. Vascular access problems are the single most important cause of morbidity among these patients. The underlying problem is the creation of intimal hyperplasia at the site where the graft is sutured to the vein. Intimal hyperplasia is what we currently treat in the coronary arteries when stents fail. This is why we are excited about this trial and the opportunity for Novoste to

assist in treating these patients who have a very poor quality of life and very limited therapeutic options.

We are very pleased to report that the FDA on February 18, 2003, approved the revised protocol for the BRAVO trial. The BRAVO trial, which enrolled its first patient in June 2002, investigates the safety and efficacy in treating venous outflow stenosis in arterial-venous dialysis grafts. The new protocol allows us to remove many of the obstacles to accelerating the rate of enrollment. In addition to allowing follow-up at the end of three months instead of six months, the success of the trial is now measured by the absence of re-intervention to keep the graft open. We would expect to complete enrollment by year-end 2003 and thus generate revenue in 2004.

Our other growth opportunity is to use VBT to treat peripheral artery disease. Femoral and popliteal vessels generally have a 35% – 55% restenosis rate. There are about 220,000 patients among the more than 2 million patients with peripheral artery disease who are treated through vascular intervention. While the disease is similar to that found in coronary arteries, there are many differences, including the vessel size and length of lesions. Many of our clinical investigators believe we have the technology that will permit a more clinically efficacious therapy.

The opportunity for Novoste lies in the fact that both of these potential markets are more than twice the size of our existing coronary VBT business. Obviously this represents a very attractive opportunity for your Company and one that is being vigorously pursued by all of the Novoste team.

Outlook

Right now, many view Novoste as a one-product company. I believe that as we obtain greater distinction this year from product introductions or new treatment options with VBT, we will move away from that perception. Already we have made changes to align our organizational structure with our market opportunity. Our people – our greatest asset – have already demonstrated their mettle, having performed so well during a time of considerable stress. We have a strong cash position and we project that revenues will be higher in 2003 than 2002. Finally, the Novoste team is focused only on one thing: vascular brachytherapy – currently in cardiology – and extending applications to two very promising areas, A-V grafts and peripheral artery disease. Resilient and energized, we are eager to move ahead.

Thank you for your support and your patience as the Company takes the necessary steps to assure profitability and future growth.

Sincerely,

Al Novak
President and Chief Executive Officer

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A
(Amendment No. 1)

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

For the fiscal year ended December 31, 2002.

☐ 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	**30093**
(Address of principal executive offices)	**(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 ☒ 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/A or any amendment to this Form 10-K/A. ☐

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

As of March 14, 2003, there were 16,351,953 shares of Common Stock outstanding. The aggregate market value of voting stock held by non-affiliates of the Registrant was approximately $71,882,455 based upon the closing sales price of the Common Stock on June 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 June 28, 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 the 2003 Annual Meeting of Stockholders, which the Registrant intends to file not later than 120 days following December 31, 2002, are incorporated by reference to Part III of this Form 10-K/A Report.

Explanatory Note

This Amendment No. 1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002 is being filed to correct several typographical and processing errors that occurred while the Company was preparing the original Annual Report on Form 10-K for filing with the SEC via the EDGAR system and to correct or revise certain disclosures therein. This Amendment No. 1 amends and restates the original Annual Report in its entirety.

NOVOSTE CORPORATION
FORM 10-K
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Cautionary Note Regarding Forward-Looking Statements

The forward-looking statements in this Form 10-K are made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended. Our operating results and financial condition have varied and may in the future vary significantly depending on a number of factors. Statements in this Form 10-K which are not strictly historical statements, including, without limitation, statements regarding management's expectations for future growth and plans and objectives for future management and operations, domestic and international marketing and sales plans, product plans and performance, research and development plans, management's assessment of market factors, as well as statements regarding our strategy and plans, constitute forward-looking statements that involve risks and uncertainties. In some cases these forward-looking statements can be identified by the use of words such as "may," "will," "should," "expect," "project," "predict," "potential" or the negative of these words or comparable words. The factors listed under "Certain Factors Which May Affect Future Results" in Part I, Item 1 – "Business", among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon our business, financial condition, and results of operations. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Accordingly, you are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made.

PART I

ITEM 1. BUSINESS

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

GENERAL

Novoste, a Florida corporation, has developed the Beta-Cath™ 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 restenosis. Restenosis, the renarrowing of a previously treated artery, is the major limitation of percutaneous coronary angioplasty 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 15% of the patients who receive stents. In August 1998, we qualified to apply CE marking to the Beta-Cath™ System. CE marking is a regulatory approval and is a requirement to sell our device in most of the European Union. We commenced the active marketing of our device in the European Union in January, 1999. On November 3, 2000, Novoste received U.S. marketing approval from the United States Food and Drug Administration ("FDA") for the Beta-Cath™ 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™ System with a 40-millimeter source train during 2001 and the 60-millimeter source train and smaller, next generation 3.5 French catheter and source train in early 2002.

Novoste was incorporated in Florida in 1987 and remained dormant until May 22, 1992 (date of inception) at which time it began operations. Novoste has its principal operations in the United States and sales and distribution in Western Europe, Canada, Asia and South America. Novoste markets it products through a direct sales force in the United States and a combination of direct sales representatives and independent distributors in markets outside the United States. All of our revenues have been generated from the marketing of the Beta-Cath™ System and during 2002, 94% 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 under Notes To Consolidated Financial Statements, Note 12. Segment Information.

Available Information. Novoste files annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy any document the Company files at the SEC's public reference room at Room 1024, 450 Fifth Street, NW, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for information on the public reference room. The SEC maintains a website that contains annual, quarterly and current reports, proxy statements and other information that issuers (including Novoste) file electronically with the SEC. The SEC's website is http://www.sec.gov.

Novoste's website is http://www.novoste.com. The Company makes available free of charge through its internet site its annual reports on Form 10-K; quarterly reports on Form 10-Q; current reports on Form 8-K; and any amendments to those reports filed or furnished pursuant to the Securities Exchange Act of 1934 (the "Exchange Act") as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information on Novoste's website is not incorporated by reference into this report.

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 coronary artery bypass graft surgery or less invasively with a PTCA procedure.

Coronary Artery Bypass Graft Surgery (CABG). 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 percutaneous transluminal coronary angioplasty, 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 2002, 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.

Percutaneous Transluminal Coronary Angioplasty (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 cardiac catheterization labs, commonly referred to as cath labs, 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 2002, it is estimated that about 1,000,000 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 1.6 million PTCA procedures performed in 2002.

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.

Vascular Brachytherapy vs. Drug Coated Stents. Vascular brachytherapy is the delivery of radiation within blood vessels. 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 (VBT) devices in 2000 and 2001. These devices, which deliver a dose of radiation to the site of restenosis, 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. One of the drug coated stents has continued development in its current configuration and is believed to be likely to receive its approval in the second quarter of 2003 (as discussed further in "Competition; Rapid Technological Change"). Other companies are seeking to test multiple drug coatings in an effort also to produce a competitive coated stent. While not completely effective, it is believed that drugs will reduce the rate of in-stent restenosis from approximately 15% down below 10%. Novoste believes, however, that the early clinical data is not representative of the wide variety of patients that will be treated by the wide variety of physicians in typical commercial settings. Novoste believes that many of those patients who do suffer from restenosis will still benefit from treatment with vascular brachytherapy. Since the price of drug coated stents is projected to be about three times the price of traditional bare metal stents, from an economic standpoint it also may not be practical or possible for many hospitals to use drug-coated stents on all their patients. Novoste believes the cost benefit of only using vascular brachytherapy on the low percentage of failed stents is currently the most attractive financial alternative for the health care system.

THE NOVOSTE SOLUTION

The Beta-Cath™ 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 in a blocked stent, where the objective is to treat the coronary artery with minimal exposure to adjacent tissues.

The Beta-Cath™ 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 are able to reuse the radiation isotopes for up to eighteen months due to the long half-life of Strontium-90, the isotope used in the Novoste device.

OUR BUSINESS STRATEGY

Our objective is to maintain our leadership position in the vascular brachytherapy market and to generate additional revenue and profits by leveraging our distribution network and our ability to execute product development and clinical trials. Elements of our strategy include:

- Maintaining our vascular brachytherapy market leadership position by offering additional enhancements and catheter options to the Beta-Cath™ System. We've responded to customer demand in 2002 by introducing a next generation small-diameter catheter and source train, the longest radiation treatment length (60mm) available in a single dwell time and the option of a longer catheter length for the convenience of remaining outside the sterile field for non-cath lab personnel. We plan to offer additional enhancements throughout 2003 to enable interventional cardiologists greater ability to treat in-stent restenosis.
- Improving our financial performance by applying our resources to products that can generate near term revenue and profits. We are also improving our enterprise resource-planning infrastructure to provide the necessary information to operate efficiently and reduce costs. Focusing on the preservation of our existing cash balances and operating profitably will allow us to fund our operating and product development activities internally.

- Expanding into the peripheral markets for growth. We plan to focus our development and leverage our vascular brachytherapy technology into larger peripheral markets treating arterial-venous (A-V) dialysis grafts and femoral-popliteal (fem-pop) disease – where drug-coated stents are not likely to be a competitive threat. We are already enrolling patients in our BRAVO A-V Graft trial and our MOBILE Fem-Pop trial. See "Product Development on Clinical Trials."

Our goals and strategies are aimed at creating a global company that is recognized for innovative, clinically superior and economically beneficial therapeutic solutions for the treatment of vascular disease. Our vision is to be the recognized leader in providing simple solutions to complex interventional therapies.

BETA-CATH™ SYSTEM DESIGN AND ADVANTAGES

The primary components of the Beta-Cath™ System are: radiation source train, transfer devices and delivery catheter.

Radiation Source Train. The beta radiation administered by the Beta-Cath™ System emanates from a "train" of several miniature sealed sources containing Strontium-90 (Strontium/Yttrium), a beta-emitting radioisotope. We currently manufacture trains in 2 diameters and 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™ System safer (less radiation exposure to cath lab personnel and shorter patient treatment dwell times versus Gamma) 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 reused for up to eighteen months and deliver a consistent dose in a short period. 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 from the transfer device prior to the return of the radiation sources to the device; and
- 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 to 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 two versions of the catheter in the United States: the Beta-Cath™ 5.0 French(F) System which fits over the guidewire used in the PTCA procedure, commonly known as an "over the wire" catheter and our next generation 3.5F distal monorail "rapid exchange" version which we refer to as the Beta-Cath™ 3.5F System.

The Beta-Cath™ System is used in a cath lab by an interventional cardiologist in conjunction with a radiation oncologist or designated authorized user. 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. We believe the Beta-Cath™ System is cost-effective, principally by reducing the need for costly revascularization procedures often required following treatment of in-stent restenosis.

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

- *Excellent economic cost benefit.* The Beta-Cath™ System is applied only when and where it is needed to treat in-stent restenosis lessions.
- *Site-specific Therapy.* The Beta-Cath™ System is designed to confine radiation exposure to the targeted intervention area.
- *Short Procedure Times.* The Beta-Cath™ 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™ System is designed to be easily adopted and used by the interventional cardiologist. The Beta-Cath™ 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™ 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™ 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

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

Clinical trials are administered by our internal clinical and regulatory staff. We also use consultants to monitor the clinical sites and to assist in training and have engaged independent contract research organizations and consultants to compile data from the trials and to perform statistical and reimbursement analyses.

Research and development expenses, which include the cost of clinical trials, for the years ended December 31, 2002, 2001, and 2000 were approximately $13.3 million, $12.8 million and $17.1 million, respectively. We have conducted numerous clinical trials to provide the basis for approval by the FDA of several versions of the Beta-Cath™ System.

Additional Beta-Cath™ System Approvals

During 2001, Novoste applied to the FDA for approval to market two additional Beta-Cath™ System products. The Beta-Cath™ 3.5F System, Novoste's next generation smaller diameter catheter system received marketing approval from the FDA in February, 2002. The Beta-Cath™ 3.5F 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™ System 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)). These 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™ 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 or that clinical trials will prove that the product is safe and effective for the treatment or therapy.

Bravo Trial

In June 2002, Novoste received approval for an investigational device exemption (IDE) application to the FDA for its CORONA™ System to treat non-thrombotic arterial-venous dialysis graft stenosis. In February 2002, Novoste received approval for a major modification to the BRAVO trial to include thrombotic 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, approved by the FDA, is a prospective, randomized, multi-center, placebo-controlled trial investigating the safety and efficacy of the CORONA™ System to treat venous outflow stenosis in arterial-venous dialysis grafts.

The BRAVO trial protocol will include 215 patients who will be assigned at random for either conventional treatment or conventional treatment plus radiation. The trial is expected to be performed in 30 sites in North America. We anticipate completion of the enrollment of the 215 patients in the second half of 2003. Provided the trial is successful we intend to file, in 2004, an application to obtain pre-market approval from the FDA to sell the CORONA™ 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 any earlier than six months after submission.

Mobile Trial

Novoste is developing the CORONA™ System to deliver Beta vascular brachytherapy to treat patients with peripheral artery disease (restricted blood flow in the upper legs). Novoste believes that there is currently no effective treatment of diffuse peripheral artery disease, which can range from debilitating by limiting a patient's ability to walk without pain, all the way to amputation, for patients who suffer from this disease. Symptomatic peripheral artery disease affects over 1.25 million patients annually in the U.S. The CORONA™ System differs from the Beta-Cath™ System by the addition of a balloon-based delivery system which allows for the treatment of large 4mm–8mm diameter vessels.

In December 2001, Novoste began its MOBILE (MOre patency with Beta In the Lower Extremity) trial. The MOBILE trial will include 410 patients from 30 sites in North America and Europe. Patients will be assigned at random for either standard percutaneous catheter-based revascularization therapy followed by vascular brachytherapy or standard therapy alone.

SALES AND MARKETING

Novoste has its U.S. sales and marketing management located in our corporate office in Norcross, Georgia and our European operation is located in Krefeld, Germany.

We have recruited, trained and deployed a qualified and experienced sales organization made up of field management, sales representatives and clinical trainers. Our marketing organization is also made up of professionals experienced in cardiology and vascular medicine as well as medically applied radiation. At the end of the year, the Sales and Marketing organization consisted of 69 employees.

We market and sell directly into the markets of the U.S. and most of Europe and Canada and we work through our distributor network for the rest of the world where the market conditions are viable for our technology.

Novoste directs its sales and marketing efforts primarily at the prominent domestic and international cardiac catheterization laboratories that perform the majority of the interventional cardiology procedures. We believe that these hospitals control the majority of procedures and will utilize new coronary technologies such as the Beta-Cath™ System for treating restenosis. Our 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. All customers must be trained, proctored and certified, pursuant to FDA requirements, by Novoste before they are eligible to do cases independently.

We also periodically meet with clinicians to share ideas regarding the marketplace, existing products, procedure techniques, products under development and existing or proposed research projects.

Our direct sales activities require contact with all of the medical specialists involved in vascular brachytherapy: cardiologists, radiation therapists and medical physicists as well as hospital administration, which results in a lengthy sales process. In addition to our multidiscipline sales force calling on these customers, we have a team of medical physicists who help the hospitals through this licensing process with both the NRC and agreement states. Amended licenses are required by every hospital before vascular brachytherapy can be performed.

We expect the existing sales force, supplemented by additional expertise for the particular application, will distribute future products currently in development or by additional personnel required to properly support the market.

We are not dependent on any single customer, and no single customer accounted for more than 10% of revenue in 2002.

MANUFACTURING, SOURCES OF SUPPLY AND SCALE-UP

Our manufacturing operations are required to comply with the FDA's quality system regulations, which included an inspection of our manufacturing facilities prior to pre-market approval of the Beta Cath™ System. 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 supplier certification program. All suppliers of components must also be in compliance with Novoste's requirements and the FDA's quality system regulations.

Beta Radiation Source Train Suppliers

Beginning in 1996, Novoste contracted with Bebig Isotopentechnik Medizintechnik (Bebig), a German corporation, to equip a production site for the production of radioactive sealed Strontium-90 seed trains.

On June 20, 2001, the Company entered into a new manufacturing and supply agreement with Bebig to manufacture and supply the Company with 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. All product purchases are credited against the annual guaranteed payment. 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, 2002, 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 Strontium-90 seed trains at an agreed-upon base price.

On October 14, 1999, Novoste signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH (AEA) for a second source of radioactive seed trains and for the development of smaller diameter radiation seed trains. The agreement provided for the construction of a production line to be finished in two phases. The first phase, the design phase, was completed in February 2001 and the second phase, the construction phase, was completed in October 2002. The completion of the first phase provided Novoste with access to a limited supply of the smaller diameter radiation source by using the design equipment to produce the smaller diameter radiation seed trains. Payments to cover the cost of this production line were paid by Novoste as construction progressed. 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. Annual production commitments and prices are still to be determined by Novoste and AEA; however, Novoste anticipates that the terms will be similar to those currently in effect.

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 and electronic components 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, Novoste's ability to produce the related product in a timely manner could be adversely affected. Novoste attempts to mitigate these risks by working closely with key suppliers regarding the Company's product needs and the maintenance of strategic inventory levels.

Supply of Other Components by Third Parties

Through 2002, Novoste relied on Plexus Corporation as third party manufacturer for the hand-held transfer device. During 2002, Novoste began a project to manufacture the transfer devices at its Norcross location. FDA approval is expected for this manufacturing change in the summer of 2003. While the Company believes it will

be better positioned to control transfer device design, lead time, product availability and overall transfer device cost, our inability to obtain sub-assemblies and components from suppliers could have a material adverse effect on our ability to manufacture the Beta-Cath™ System and, therefore, on our ability to market the Beta-Cath™ System. The Company will continue its efforts to mitigate the risks associated with this issue by continued careful review and proactive control of its inventories, and ensuring adequate safety stock of both finished devices and components is maintained.

PATENTS AND PROPRIETARY TECHNOLOGY

Our policy is to protect our proprietary position by, among other methods, filing United States and foreign patent applications. We were issued United States Patent No. 5,683,345 on November 4, 1997, Patent No. 5,899,882 on May 4, 1999, No. 6,013,020 on January 11, 2000, No. 6,261,219 on July 17, 2001 and Patent No. 6,306,074 on October 23, 2001, all of which relate to both or either the Beta-Cath ™ System with an over-the-wire catheter of the Beta Cath™ System with a "rapid exchange" catheter. We also have several additional United States applications pending covering aspects of our Beta-Cath™ System. 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 and certain other regions or 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 Nos. 5,683,345; 5,899,882; 6,013,020; 6,261,219 and 6,306,074 may not offer any protection to us because competitors may be able to design functionally equivalent devices that do not infringe these patents. Any of the patients 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™ System does not infringe any claim of the Dake patent as reexamined.

In May 1997, Guidant Corporation ("Guidant") acquired NeoCardia together with the rights under the Dake patent. Guidant currently markets and distributes products that compete with the Beta-Cath™ System and has significantly greater capital resources than Novoste. Novoste does not believe that its products infringe the Dake patent or that an action by Guidant for infringement would have merit.

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™ 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™ 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™ 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™ System.

All of the physicians on staff at Emory who were involved in the development of the Beta-Cath™ System, have assigned their rights in the technology, if any, to Emory and/or Novoste. In addition, we have entered into a license agreement with one of the physicians and under the terms of this agreement, he is entitled to receive a royalty on the net sales of the Beta-Cath™ System (excluding consideration paid for the radioactive isotope), up to a maximum, over the term of the agreement, 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 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 noncompetitive.

Many of our competitors and potential competitors have substantially greater resources than we do and also have greater resources and expertise in the area of research and development, obtaining regulatory approvals, manufacturing and marketing. Our competitors and potential competitors may succeed in developing, marketing and distributing technologies and products that are more effective than those we will develop and market or that would render our technology and products obsolete or noncompetitive. 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.

Both Johnson & Johnson (J&J) and Guidant offer vascular brachytherapy products that compete directly with Novoste Beta-Cath™ System 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™ System, is a gamma radiation vascular brachytherapy device. Although the CHECKMATE™ System received approval at the same time as our Beta-Cath™ System, we believe the Beta-Cath™ System competes effectively against the CHECKMATE™ System because of the ease of use of beta radiation over gamma. In November 2001, Guidant received FDA approval to market the GALILEO™ Intravascular Radiotherapy System. The GALILEO™ System is a beta radiation system as is the Beta-Cath™ System and the Company competes with Guidant based upon price and product performance. For 2002 the Beta-Cath™ System maintained approximately 60% of the vascular brachytherapy market worldwide.

Many of these same companies and others are researching coatings and treatments to coronary stents, commonly referred to as drug eluting stents, which could reduce restenosis and would possibly be more acceptable to a medical community already experienced at using stents. Their development represents a potentially revolutionary advance in cardiovascular treatment. During 2002 drug eluting stents began to enter the European market and we anticipate initial US entry in the second quarter of 2003. We expect these introductions to reduce the use of metallic stents in the US and, if the reduction of in-stent restenosis is significant, it could have a negative impact on the ultimate acceptability of vascular brachytherapy

GOVERNMENT REGULATION

United States

Our Beta-Cath™ 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™ 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 is a "significant risk device," 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, 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 trials 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. 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, called the quality systems regulations (QSR). The QSR 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 or misleading 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. What constitutes a "reasonable basis" may depend on the context of the claim and the level of substantiation expressly or impliedly claimed in the advertising.

Our business involves the import, export, manufacture, distribution, use and storage of Strontium-90 (Strontium/Yttrium), the beta-emitting radioisotope utilized in the Beta-Cath™ System's radiation source train. Accordingly, manufacture, distribution, use and disposal of the radioactive material used in the Beta-Cath™ System in the United States is subject to federal, state and/or local rules relating to radioactive material. The State of Georgia Department of Natural Resources (Georgia DNR) issued a sealed source and device registration certificate for the Company's Beta-Cath™ System on August 4, 2000, allowing it to be listed on the Nuclear Regulatory Commission's Sealed Source and Device Registry. The Georgia 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™ System. In addition, we must comply with NRC, Georgia DNR 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™ 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™ System. Depending on the state in which the hospital is located, its license amendment will be processed by the responsible department in states that have agreed to such arrangements, or by the NRC. Obtaining any of the foregoing radiation-related approvals and licenses can be complicated and time consuming.

Novoste is 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 the CE mark to the Beta-Cath™ 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™ 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™ 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™ 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™ 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 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, 2002 we directly employed 306 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.

CERTAIN FACTORS WHICH MAY AFFECT FUTURE RESULTS

In connection with the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, set forth below are cautionary statements identifying important factors that could cause actual events or results to differ materially from any forward-looking statements made by or on behalf of us, whether oral or written. We wish to ensure that any forward-looking statements are accompanied by meaningful cautionary statements in order to maximize to the fullest extent possible the protections of the safe harbor established in the Private Securities Litigation Reform Act of 1995. Accordingly, any such statements are qualified in their entirety by reference to, and are accompanied by, the following important factors that could cause actual events or results to differ materially from our forward-looking statements. For additional information regarding forward-looking statements, please read the "Cautionary Note Regarding Forward-Looking Statements" section beginning on page 3.

We Are Dependent On The Successful Commercialization Of One Product, The Beta-Cath™ System.

We began to commercialize the Beta-Cath™ System in the United States in November 2000. Substantially all of our revenue in 2002 was from sales in the United States. We anticipate that for the foreseeable future we will be solely dependent on the continued successful commercialization of the Beta-Cath™ System; however; in the future we may be unable to manufacture the Beta-Cath™ System in commercial quantities at acceptable costs or to demonstrate that the Beta-Cath™ System is an attractive and cost-effective alternative or complement to other procedures, including coronary stents, competing vascular brachytherapy devices, or drug coated stents. Because the Beta-Cath™ System is our sole near-term product focus, we could be required to cease operations if new technology rendered vascular brachytherapy non-competitive. Our failure to continue commercialization of the Beta-Cath™ System would have a material adverse effect on our business, financial condition and results of operations.

Drug-Eluting Stents Or Other New Technology Could Render Vascular Brachytherapy Generally Or The Beta-Cath™ System In Particular Noncompetitive Or Obsolete.

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

J&J and Guidant compete directly with Novoste for market acceptance of vascular brachytherapy and each has substantially greater resources and experience at introducing new products than does Novoste. We may not be able to compete effectively against J&J or Guidant in the vascular brachytherapy market if they develop products, which are more effective than our products and are preferred by the international cardiologists in treating in-stent restenosis. We would also be negatively affected if these competitors were successful at competing solely by reducing the price of their products because of our sole dependence on the Beta-Cath™ System.

Many of these same companies and others are researching coatings and treatments to coronary stents that could reduce restenosis and possibly be more acceptable to a medical community already experienced at using stents. Clinical trial results have reported a significant reduction in restenosis rates to below 10%. In addition, J&J recently received unanimous approval by a FDA advisory panel that its drug eluting stent be approved for distribution in the U.S. Full FDA approval may occur as early as the second quarter of 2003. If drug-eluting stents are proven effective at reducing restenosis and are widely adopted by the medical community, these stents could have a material adverse effect on Novoste's business.

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

Our policy is to protect our proprietary position by, among other methods, filing United States and foreign patent applications. On November 4, 1997 we were issued United States Patent No. 5,683,345, on May 4, 1999

we received United States Patent No. 5,899,882 (which is jointly owned by us and Emory University) and on January 11, 2000 we received United States Patent No. 6,013,020, all related to the Beta-Cath™ System. We also have several additional United States applications pending covering other aspects of our Beta-Cath™ System. The United States Patent and Trademark Office has indicated that certain claims pending in another United States application are allowable. With respect to the above identified United States Patents and our other pending United States patent applications, we have filed, or will file in due course, counterpart applications in the European Patent Office and certain other countries.

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

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

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

Compliance With Applicable Government Regulations Will Be Expensive And Difficult.

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

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

any changes that could affect safety or effectiveness, additional approvals will be required by the FDA. Such changes include, but are not limited to new indications for use, the use of a different facility to manufacture, changes to process or package the device, changes in vendors to supply components, changes in manufacturing methods, changes in design specifications and certain labeling changes. Failure to receive or delays in receipt of FDA approvals, including the need for additional clinical trials or data as a prerequisite to approval, or any FDA conditions that limit our ability to market our systems, could have a material adverse effect on our business, financial condition and results of operations.

Additionally, in October 2002, the FDA began to require the payment of fees for the review of submissions requesting clearance or approval to market medical products, called user fees. Submissions requesting clearance or approval for marketing can be assessed a fee of approximately $2200 for a Section 510(k) pre-market notification or approximately $33,000 to approximately $154,000 for a pre-market application or supplement (depending on the type of submission).

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

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

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

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

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

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

kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

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

The sale and use of our products could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time-consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

Our Quarterly Operating Results May Vary

Our operating results have fluctuated significantly in the past on a quarterly basis. We expect that our operating results may fluctuate significantly from quarter to quarter and we may experience losses in the future depending on a number of factors, including the extent to which our products continue to gain market acceptance, the rate and size of expenditures incurred as we expand our domestic and establish our international sales and distribution networks, the timing and level of reimbursement for our products by third-party payors, and other factors, many of which are outside our control.

We Are Highly Dependent On Key Personnel.

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

Our Lack Of Redundant Manufacturing Facilities Could Harm Our Business.

We assemble all of our products at our facilities in Norcross, Georgia. The loss of these facilities would likely impede our manufacturing and sales efforts, which would materially and adversely affect our business and financial condition. Should this occur we would have to depend on outsourcing to produce our catheter products.

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

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

Under our amended and restated articles of incorporation, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences and privileges of those shares without any further vote or action by our shareholders. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any shares of preferred stock that may be issued in the future.

While we have no present intention to authorize any additional series of preferred stock, such issuance, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could also have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock. The preferred stock may have other rights, including economic rights senior to the common stock, and, as a result, the issuance thereof could have a material adverse effect on the market value of the common stock.

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

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

Item 2. PROPERTIES

The Company's facilities are located in Norcross, Georgia and consist of two separate locations totaling approximately 90,000 square feet of leased office and manufacturing space, including a 3,000 square foot class 100,000 clean room. The Company also leases 3,000 square feet in Krefeld, Germany which serves as its European customer service and distribution headquarters.

Item 3. LEGAL PROCEEDINGS

Novoste is subject to legal claims and assertions in the ordinary course of business. We are not aware of any such assertions that would have a material effect on Novoste.

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

Not applicable

Item 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers are as follows:

Name	Age	Position
Alfred J. Novak	55	President and Chief Executive Officer
Donald J. Webber	40	Chief Operating Officer
Edwin B. Cordell, Jr.	44	Vice President, Finance and Chief Financial Officer
David C. Field	44	Vice President, New Technology
Andrew Green	34	Vice President, Regulatory Affairs
Daniel G. Hall	56	Vice President, Secretary and General Counsel
Adam G. Lowe	40	Vice President, Quality Assurance
Pia Mikkelsen Lynch, M.D	42	Vice President, Global Clinical Affairs
Susan D. Smith	53	Vice President, Human Resources
Robert N. Wood, Jr.	48	Vice President, Sales

Alfred J. Novak. Mr. Novak joined Novoste Corporation and was elected President and Chief Executive Officer on October 16, 2002. Mr. Novak is a Founding Member of Syntheon LLC, a company focused on minimally invasive medical devices for the vascular and gastroenterology markets. He serves as Chairman of the Board of Directors of Orbus Medical Technologies, Inc. and is also Chairman of Transurgical, Inc., two start-up medical device companies focused in cardiology. Between 1996 and 1998 Mr. Novak served as President and Chief Executive Officer of Biosense, Inc. Mr. Novak was employed at Cordis Corporation between 1984 and

1996 in a variety of management positions culminating in his election as Vice President and Chief Financial Officer and a member of the executive committee in August, 1989. Al Novak received his MBA from the Wharton School of the University of Pennsylvania and earned his B.S. at the U.S. Merchant Marine Academy.

Donald J. Webber. Mr. Webber joined Novoste 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 Novoste 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.

David C. Field. Mr. Field joined Novoste in April 2001 as Vice President, New Technologies. Prior to joining Novoste, Mr. Field served as Director of Business Development for the Peripheral Technologies Division of C.R. Bard, Inc. From 1995 to 1998 he was the Director of Marketing for the same division of C.R. Bard, Inc. 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 from the University of Maryland and an A.D. in Engineering from the State University of New York in Canton.

Andrew M. Green. Mr. Green joined Novoste in 1996. Prior to 1996 he served as Scientific Reviewer for the U.S. Food and Drug Administration (FDA), where he reviewed scientific, technical, pre-clinical and clinical data submitted in support of and effectiveness of interventional cardiology medical devices. Mr. Green holds a M.S. degree in Bioengineering and a B.S. degree in Biological Science, both from Clemson University.

Daniel G. Hall. Mr. Hall joined Novoste 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 Novoste in June 1999 as our Vice President, Quality Assurance. 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.

Pia Mikkelsen Lynch, M.D. Dr. Lynch joined Novoste in April 2002 from Elan Pharmaceutical Research Corporation where she served as Director, Clinical Research since 1997. In this role, she was responsible for developing business and clinical strategies for various projects in multi-therapeutic areas, as well as managing all worldwide clinical development programs for Phase I through IV studies. From 1996 to 1997, Dr. Lynch served as Medical Project Manager, at Worldwide Clinical Trials, Inc., where she directed global clinical research organization services for Phase I through III clinical trials. From 1995 to 1996, she was employed as a Medical Consultant with Integrated Micro Technologies, Inc. and from 1991 through 1994, Dr. Lynch served as a post-graduate research fellow in the Department of Hematology and Oncology at the University of Aarhus, Denmark. Dr. Lynch holds a Doctor of Medicine (M.D.) degree from the University of Aarhus, Denmark.

Susan D. Smith. Ms. Smith joined Novoste in March 1996. 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.

Robert N. Wood, Jr. Mr. Wood joined Novoste 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 to 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 SHAREHOLDER MATTERS

Our 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 14, 2003 was 99 excluding beneficial owners of shares are 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. Business—Certain Factors which May Affect Future Results—Issuance of preferred stock may adversely affect rights of holders of common stock or delay or prevent a change of control of the Company" 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, 2001		
March 31, 2001	$38.8700	$14.0000
June 30, 2001	$25.7500	$13.6200
September 30, 2001	$25.2500	$ 5.9300
December 31, 2001	$13.3100	$ 5.7300
Year Ended December 31, 2002		
March 31, 2002	$11.2700	$ 6.5500
June 30, 2002	$ 8.7500	$ 4.6200
September 30, 2002	$ 5.0500	$ 3.3500
December 31, 2002	$ 7.2200	$ 3.9690

On March 14, 2003, the last reported sale price for the Common Stock was $7.95.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected financial data shown below for the fiscal years ended December 31, 2002, 2001 and 2000, and as of December 31, 2002 and 2001, have been taken or derived from our audited financial statements included in this Form 10-K. The selected financial data set forth below for the fiscal years ended December 31, 1999 and 1998, and as of December 31, 2000, 1999 and 1998, have been derived from our audited financial statements for those years, which are not included in this Form 10-K. The selected consolidated financial data set forth below should be read in conjunction with the consolidated financial statements and related notes thereto and with "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" included elsewhere in this Form 10-K.

	For The Year Ended December 31,				
	2002	2001	2000	1999	1998
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Net sales and revenues	$ 69,030	$ 69,908	$ 6,530	$ 1,823	$ 19
Costs and expenses:					
Cost of sales	27,313	19,164	4,258	1,642	117
Impairment and related charges	6,900	—	—	—	—
Research and development	13,300	12,756	17,119	22,889	21,089
Sales and marketing	26,875	34,654	15,651	6,606	3,074
General and administrative	8,335	9,324	6,321	3,775	2,528
Restructuring and other expenses	—	1,214	—	—	—
Loss from operations	(13,693)	(7,204)	(36,819)	(33,089)	(26,789)
Other income (expense), net	642	2,095	3,746	2,169	2,127
Net loss	$ (13,051)	$ (5,109)	$ (33,073)	$(30,920)	$(24,662)
Basic and diluted net loss per share (1)	$ (0.80)	$ (0.32)	$ (2.13)	$ (2.30)	$ (2.34)
Weighted average shares outstanding (1)	16,268	16,152	15,517	13,433	10,536
Consolidated Balance Sheet Data:					
Working capital	$ 30,496	$ 40,482	$ 53,742	$ 38,821	$ 21,797
Total assets	67,519	82,911	77,073	49,367	29,482
Long-term liabilities	5	203	401	—	—
Accumulated deficit	(134,434)	(121,384)	(116,275)	(83,201)	(52,281)
Total shareholders' equity	52,765	64,728	67,042	43,065	24,517

(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

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™ System. The Company commenced the active marketing of the Beta-Cath™ 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™ 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 to over 400 in 2002.

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™ System in the U.S. At December 31, 2002 we had an accumulated deficit of approximately $134.4 million. The Company experienced its first net operating profit in the third quarter of 2001. We expect to achieve an operating profit in 2003 as we continue to allocate resources to leverage our existing manufacturing operations, both internally and with outside vendors. We also 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 resources than Novoste including J&J and Guidant. Both J&J and Guidant have introduced vascular brachytherapy products that compete with our Beta-Cath™ System. A new technology called drug-coated stents poses additional competitive threats in treating restenosis. We may not be able to sustain an acceptable level of market demand for the Beta-Cath™ System if this technology is successfully introduced. Failing to sustain our current level of demand could significantly reduce revenues and affect our ability to become 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 may 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 our significant accounting policies.

Revenue Recognition

Revenue from the sale of products is recorded when an arrangement exists, delivery has occurred and services have been rendered, the seller's price is fixed and determinable and collectability is reasonably assured. 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™ 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 generally no purchase commitments and no provisions for cancellation of purchases. Novoste or the distributor may cancel the distributor agreements at any time.

Revenue from sales of catheters directly to hospitals is recognized upon shipment after the hospital has leased a Beta-Cath™ 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 or number of usages. This amount is included in cost of sales as incurred. No other post-sale obligations exist.

The Company sells its catheters with no right of return except in cases of product malfunction or shipping errors. In connection with the approval to relaunch the 3.5F catheter system on January 6, 2003 the Company plans to exchange some 5F catheters for 3.5F catheters for its customers. A reserve has been recorded against revenue for known returns and an estimate of unknown returns. The exchange of these catheters is expected to continue in the future until the 3.5F system had been fully launched to a significant majority of customer sites. At December 31, 2002, the Company had recorded a reserve for approximately $2,150,000 to recognize the 5F catheters purchased prior to December 31, 2002 that were expected to be returned in the future in exchange for 3.5F catheters.

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 using the straight-line method. Depreciation begins at the time the Beta-Cath™ System is placed into service. Valuation reserves are recorded for the balance of unamortized costs of TDs and RSTs that are not available for use by a customer due to expiration or unsatisfactory performance measures.

The Company has invested significant resources to acquire RSTs and TDs that make up the Beta-Cath™ 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 derived from available information provided by the Company's Sales and Marketing organizations. 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.

During the second quarter of 2002, Novoste decided to concentrate marketing and development efforts on the 3.5 F diameter Beta-Cath™ System. Accordingly, the Company evaluated the recoverability of the carrying value for 5.0F devices and other assets to determine if an impairment charge was necessary. The Company performed this evaluation in accordance with the provisions of Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. Based on this evaluation, the Company determined that an impairment and other related charges of $6.9 million was warranted (See Note 8). Management will continue to evaluate its long-lived assets in accordance with SFAS NO. 144.

Stock Based Compensation

The Company uses the intrinsic value method for valuing its awards of stock options and restricted stock and recording the related compensation expense, if any, in accordance with Accounting Principles Board Opinion (APB) No. 25, Accounting for Stock Issued to Employees, and related interpretations. 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. No compensation expense is recognized for stock option grants to employees for which the terms are fixed and the exercise price is equal to the fair value of the shares at the date of the grant.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation 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. The amount recorded in the allowances is based primarily on management's evaluation of the financial condition of the customers. If the financial condition of any 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. Actual losses from uncollectible accounts are charged against the allowance when it is determined that the account cannot be collected. Ending balances for the allowance for doubtful accounts were $1,135,000 and $878,000 for the years ending December 31, 2002 and 2001, respectively. Bad debt expenses were $372,000 in 2002 and $590,000 in 2001. Actual write-offs of balances due were $246,000 in 2002 and $83,000 in 2001. A portion, $131,000, of the increase in the allowance for doubtful accounts in 2002 was due to increases in the exchange rate of accounts denominated in Euros during 2002.

Inventories

Novoste values its inventories at the lower of cost or market value on a first-in, first-out (FIFO) basis. Provisions are recorded for excess or obsolete inventory equal to the cost of the inventory. Shelf-life expiration or replacement products in the marketplace may cause product obsolescence. If actual product demand and market conditions were less favorable than those projected by management, additional provisions might be required which would negatively impact operating profits. Novoste evaluates the adequacy of these provisions quarterly. Inventory reserves were $844,000 at December 31, 2002 and $15,000 at December 31, 2001. The increase was due primarily to revenues against 3.5F catheters following the voluntary recall in August 2002.

RESULTS OF OPERATIONS

Comparison of Years Ended December 31, 2002 and 2001

The net loss for the year ended December 31, 2002 was $13,051,000, or $.80 per share, as compared to $5,109,000, or $0.32 loss per share, for the year earlier.

Net Sales and Revenues. Net sales and revenues were $69,030,000 for the year ended December 31, 2002 as compared to $69,908,000 for the year ended December 31, 2001. The decrease was due to the voluntary recall of the 3.5F catheters in August 2002. Revenues recorded in the United States for the year ended December 31, 2002 were $64,746,000 as compared to $64,697,000 for the year ended December 31, 2001. Comparatively,

international revenue decreased 17.8% to $4,284,000 in 2002 compared to $5,212,000 in 2001. Factors impacting both U.S. and international revenue included the voluntary recall of the 3.5F catheters in August 2002 as well as increased competition in the U.S.

Cost of Sales. Cost of sales for the year ended December 31, 2002 were $34,213,000, including the $6,900,000 of impairment and related charges, resulting in a gross margin of $34,817,000 or 50.4% as compared to cost of sales of $19,164,000 and a gross margin of $50,744,000 or 72.6% of net sales for the year ended December 31, 2001. The decrease in gross margin on both an absolute and percentage basis is impacted partially due to the introduction of the 3.5F system during the second quarter of 2002 and the additional amortization and service costs associated with having a second Beta-Cath™ System in the market. However, the margins were also impacted by the impairment and other related charges of $6,900,000 taken in the second quarter of 2002 against the carrying value of 5F assets. 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 (including device servicing and repair costs, and radiation shipping and disposal costs) used in the Beta-Cath™ System.

Research and Development Expenses. Research and development expenses increased 4.3% to $13,300,000 for the year ended December 31, 2002 from $12,756,000 for the year ended December 31, 2001. This increase was primarily the result of the launch of both the MOBILE and BRAVO clinical trials. Novaste anticipates increasing research and development expenses in 2003 as it pursues substantial completion of these two trials.

Sales and Marketing Expenses. Sales and marketing expenses decreased 22.4% to $26,875,000 for the year ended December 31, 2002 as compared to $34,654,000 for the previous year. The decrease represents lower costs to distribute the catheter products considering that a significant portion of customer sites were added during 2001 and 2002 included costs for maintaining those accounts and launching (and subsequently recalling) the 3.5F Beta-Cath™ System. Sales and marketing expenses were also reduced based upon consolidation of European facilities begun in 2001 and certain workforce reductions in the U.S.

General and Administrative Expenses. General and administrative expenses decreased 10.6% to $8,335,000 for the year ended December 31, 2002 from $9,324,000 for the year ended December 31, 2001. The decrease for this period was primarily the result of lower management expenses (accounting, information systems, human resources and benefits) due to the reduction in revenue growth of the Beta-Cath ™ System. In addition, salaries and expenses for the office of CEO were less in 2002 prior to the transition to our new CEO in October 2002.

Other Income. Net other income decreased 69.4% to $642,000 for the year ended December 31, 2002 from $2,095,000 for the prior year. The decrease in other income is primarily attributable to the decrease in interest income year-to-date as a result of a decrease in cash equivalent and short-term investment balances combined with falling interest rates.

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 that resulted from the commercial launch of our Beta-Cath™ System in the U.S. market.

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™ System in November 2000 which resulted in the first full year of sales in the U.S. for this product. Revenues recorded in the United States for the year ended December 31, 2001 were $64,697,000 as compared to $1,816,000 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 $5,212,000 compared to $4,713,000. 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 and this reimbursement 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 72.6% as compared to cost of sales of $4,258,000 and a gross margin of $2,272,000 or 34.8% 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. 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 (including device servicing and repair costs, and radiation shipping and disposal costs) used in the Beta-Cath™ System.

Research and Development Expenses. Research and development expenses decreased 25.5% to $12,756,000 for the year ended December 31, 2001 from $17,119,000 for the year 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™ System in November 2000.

Sales and Marketing Expenses. Sales and marketing expenses increased 121.4% to $34,654,000 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 our 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™ System in the United States.

General and Administrative Expenses. General and administrative expenses increased 47.5% 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 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.

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 Unites States in addition to termination of certain facility leases in Europe. We paid $560,000 of the restructuring charges in 2001 related to severance payments and lease payments for closed facilities and had $213,000 remaining in accrued expenses at December 31, 2001 related primarily to severance agreements and facility lease and termination payments. Additionally, Novoste expensed $440,000, the Company's total investment, as the result of an impairment of an equity method investment.

Other Income. Net other income decreased 44.1% to $2,095,000 for the year ended December 31, 2001 from $3,746,000 for the prior year. The decrease in other income is primarily attributed to the decrease in interest income. The decrease in interest income 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.

Liquidity and Capital Resources

During the year ended December 31, 2002, Novoste generated cash from operations of $10.7 million. The components of cash generated or used and reasons for change from 2002 over 2001 are as follows: (i) $9,326,000 provided from accounts receivable as collections exceeded revenues due to the slower revenue run rate in the last half of 2002, compared to the last half of 2001 and the recall of the 3.5F product beginning in August 2002 which generated catheter exchanges at no charge, (ii) $85,000 used for inventory increases, but less than 2001 due to

slower inventory growth also due to the slower revenue run rate offset by the introduction of more catheter offerings by the company necessitating greater inventory requirements per revenue dollar, (iii) $36,000 provided by a decrease in prepaid expenses as several clinical trials reached conclusion, (iv) $17,634,000 provided by a decrease in other assets offset by an increase in amortization of radiation and transfer devices and a $5,065,000 impairment charge, (v) $13,051,000 used by operating losses, (vi) $2,033,000 used by reducing accounts payables because purchases at the end of 2002 were significantly lower than the end of 2001 when the Company was getting ready to launch the 3.5F diameter catheter, (vii) $1,001,000 used by fewer accrued expenses and taxes withheld because of slower growth, and (viii) $387,000 used by a decrease in unearned revenue related to revenue recognized on radiation and transfer devices due to much lower revenues on second year leases of transfer devices.

The improvement in cash from operations during 2002 resulted from fewer resources required in 2002 to fund the opening of customer sites, expansion of the launch of the Beta-Cath™ System and the related transfer devices, radiation source trains and catheter inventory required during 2001 when Novoste opened over 300 sites. Activities related to the launch of the 3.5F Beta-Cath™ System and the subsequent voluntary recall of the 3.5F catheters were the primary uses of cash in 2002.

Net cash provided by investing activities for the year ended December 31, 2002, was $5.2 million. $20.0 million in cash was provided by shorter maturities of available-for-sale securities, $2,730,000 was used for purchase of property and equipment, but at a lower level than 2001 due to completion of manufacturing facilities, and $12,124,000 was used for the purchase of additional radiation and transfer devices, but at a lower level than 2001 as the rate of adding new customer sites slowed.

Novoste's financing activities include the purchase of treasury stock, equity offerings and borrowings and repayments of capital leases. Financing activities for the year ended December 31, 2002 used $.2 million and provided net cash of $1.7 and $56.1 million for the years ended December 31, 2001 and 2000, respectively.

In 2002, Novoste received $.5 million from the exercise of stock options, purchased $.6 million of treasury stock and repaid $.2 million for capital leases of computer equipment.

At December 31, 2002 the Company had commitments to purchase $4.4 million in inventory components of the Beta-Cath™ System over the next year.

On October 14, 1999 Novoste signed a development and manufacturing supply agreement with AEA Technologies QSA GmbH (AEA) for a second source of radioactive supply and for the development of a smaller diameter radiation source. The agreement provided for the construction of a production line to be finished in two phases. The first phase, the design phase, was completed in February and the second phase was completed in October 2002. The completion of the first phase provided Novoste with access to a limited supply of the smaller diameter radiation source by using the design equipment to produce the smaller diameter radiation seed trains. The cost of this production line was paid by Novoste as construction progressed. Depreciation of the production line began when the equipment was placed into service, in October 2002. In addition, the agreement provides for joint ownership of all intellectual property arising from the development work and that AEA may manufacture vascular brachytherapy sources only for us. Annual production commitments and prices are still to be determined by Novoste and AEA; however, Novoste anticipates that the terms will be similar to those currently in effect.

On June 20, 2001, the Company entered into a manufacturing and supply agreement with Bebig Isotopen- und Medizintechnik GmbH (Bebig), a German corporation, to manufacture and supply the Company with radioactive sealed Strontium-90 seed trains. During each calendar year under the four-year contract, the Company guarantees to pay to Bebig minimum annual payments varying amounts. 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, 2002, the Company exceeded the annual guaranteed payment.

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™ System (excluding consideration paid for the radioactive

isotope), subject to a maximum payment of $5,000,000. Royalty fees to the physician aggregated $667,540, $632,600, and $63,200 in 2002, 2001 and 2000, respectively, and have been expensed in cost of sales. Approximately $3.6 million remains to be paid.

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 $1,377,579, $1,443,967, and $146,050 in 2002, 2001 and 2000, respectively, and have been expensed in cost of sales.

The Company's principal source of liquidity at December 31, 2002 consisted of cash, cash equivalents and short-term investments of $33.6 million. The Company has a $10 million revolving line of credit with a financial institution (lender) that matures in February 2004. At December 31, 2002, 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.

At December 31, 2002, the Company was in violation of the tangible net worth covenant of the loan agreement; the lender has issued a waiver for that violation through February 28, 2003. By agreement between the Company and the lender dated March 4, 2003, the maturity date of the original loan agreement between the parties has been extended to February 27, 2004. Also as part of that modification, the tangible net worth covenant was changed and the interest rate was changed to a base of the greater of the bank's prime rate or 4.25%, plus 1%.

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, 2002.

As of December 31, 2002, we had contractual obligations as follows:

	Payments due by period				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-Term Debt	$ —	$ —	$ —	$ —	$ —
Capital Lease Obligations	183,000	178,000	5,000	—	—
Operating Leases	2,524,500	901,000	1,623,500	—	—
Purchase Obligations	4,409,000	3,159,000	1,250,000	—	—
Other Long-Term Liabilities Reflected on the Registrant's Balance Sheet under GAAP	—	—	—	—	—
Total	$7,116,500	$4,238,000	$2,878,500	$ —	$ —

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 2003. 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™ 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.

OFF-BALANCE SHEET ARRANGEMENTS

We do not maintain any off-balance sheet financing arrangements apart from the operating leases described above.

RECENT ACCOUNTING PRONOUNCEMENTS

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 July 2002, the FASB issued SFAS No. 146 Accounting for Costs Associated with Exit or Disposal Activities, which addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including certain costs incurred in a restructuring). The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The Company does not expect that the adoption of SFAS No. 146 will have a material impact on its financial statements.

In November 2002, the FASB issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees." FIN 45 requires a gurarantor to recognize, at the inception of a guarantee, a liability for the fair value of the obligation it has undertaken in issuing the guarantee. The Company will apply FIN 45 to guarantees, if any, issued after December 31, 2002. At adoption, FIN 45 did not have a significant impact on the Company's consolidated statements of operations or financial position. FIN 45 also requires guarantors to disclose certain information for guarantees, including product warranties, outstanding at December 31, 2002

In November 2002, the EITF reached a consensus on EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The Issue addresses certain aspects of the accounting for arrangements under which a vendor will perform multiple revenue-generating activities. EITF 00-21 addresses when a revenue arrangement with multiple deliverables should be divided into separate units of accounting and, if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. The Company is required to adopt the provisions of EITF 00-21 effective July 1, 2003, and the Company does not expect the adoption of EITF 00-21 to have a material impact on its results of operations or financial condition.

In December 2002, the FASB issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. SFAS 148 amends Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation,* to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method on reported results.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

Interest Rate Risk

The Company's cash and 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, 2002, the Company had $21.9 million in cash and cash equivalents with a weighted average interest rate of .91% and $11.6 million in available for sale investments with a weighted average interest rate of 2.02%. At December 31, 2001, the Company had $5.9 million in cash and 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%.

Foreign Currency Risk

International revenues from the Company's foreign direct sales and distributor sales comprised 6%, 7% and 72% of total revenues for the years ended December 31, 2002, 2001 and 2000, respectively. With the exception of the Australian, Chinese and New Zealand distributors, 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, 2002. 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, 2002 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 15, 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

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, 2002.

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, 2002, 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 AND RELATED SHAREHOLDER MATTERS

The information required by Items 403 and 201(d) 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, 2002.

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, 2002.

ITEM 14. CONTROLS AND PROCEDURES

(a) *Disclosure Controls and Procedures.* Within the 90-day period prior to the filing date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective in timely notification to them of information we are required to disclose in our periodic SEC filings and in ensuring that this information is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations.

(b) *Internal Controls.* There have been no significant changes in our internal controls or in other factors that could significantly affect those controls, including any corrective actions with regard to significant deficiencies and material weaknesses, subsequent to the date of their evaluation.

(c) *Limitations on the Effectiveness of Controls.* The company's management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our Disclosure Controls or our Internal Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Some inherent limitations in all control systems include the realities that (i) judgments in decision-making can be faulty; (ii) breakdowns can occur because of simple error or mistake; (iii) controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control; and (iv) the design of any system of controls is based in part upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART IV

ITEM 15. 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 SEC is included in the Notes to Consolidated Financial Statements; thereby eliminating the need for these schedules.

3. *Exhibits.*

The exhibits listed in the accompanying Index to Exhibits immediately following the financial statements are filed as part of this Report.

(b) *Reports on Form 8-K.*

The Registrant filed the following reports on Form 8-K during the fiscal quarter ended December 31, 2002.

(1) The Company filed a Form 8-K on October 17, 2002 (i) setting forth the content of amendments to the Company's By-Laws, which were enacted by the Board of Directors on October 16, 2002 and (ii) announcing the appointment of Alfred J. Novak as President and Chief Executive Officer of the Company.

SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the Registrant has duly caused this amendment to be signed on its behalf by the undersigned, thereunto duly authorized, on April 8, 2003.

NOVOSTE CORPORATION

By: /s/ ALFRED J. NOVAK

Alfred J. Novak
Chief Executive Officer

CERTIFICATIONS

I, Alfred J. Novak, certify that:

1. I have reviewed this annual report on Form 10-K/A of Novoste Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within these entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 8, 2003

/s/ ALFRED J. NOVAK

ALFRED J. NOVAK
Chief Executive Officer

CERTIFICATIONS

I, Edwin B. Cordell, Jr., certify that:

1. I have reviewed this annual report on Form 10-K/A of Novoste Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other executive officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 8, 2003

/s/ EDWIN B. CORDELL, JR.
EDWIN B. CORDELL, JR.
Chief Financial Officer

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, 2002 and 2001, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. 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, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

Ernst & Young LLP

Atlanta, Georgia
February 4, 2003, except for Notes 4
and 13, as to which the date is March 4, 2003

NOVOSTE CORPORATION
CONSOLIDATED BALANCE SHEETS

	December 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,928,462	$ 5,878,286
Short-term investments	11,646,800	31,683,627
Accounts receivable, net of allowance of $1,134,876 and $878,424, respectively	6,757,697	16,130,721
Inventories	3,926,879	3,746,433
Prepaid expenses and other current assets	986,197	1,023,137
Total current assets	45,246,035	58,462,204
Property and equipment, net	9,541,802	9,886,711
Radiation and transfer devices, net	11,352,801	13,534,356
Receivable from officers	282,429	144,025
Other assets	1,096,375	883,311
	$ 67,519,442	$ 82,910,607
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,176,063	$ 4,026,866
Accrued expenses	9,966,958	10,917,277
Deferred revenue	2,429,155	2,786,476
Capital lease obligations	177,451	249,212
Total current liabilities	14,749,627	17,979,831
Long-term liabilities:		
Capital lease obligations	5,201	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; 16,351,953 and 16,265,081 shares issued, respectively	163,520	162,651
Additional paid-in capital	187,813,442	187,357,044
Accumulated other comprehensive income (loss)	190,087	(408,139)
Accumulated deficit	(134,434,438)	(121,383,528)
	53,732,611	65,728,028
Less treasury stock, 118,077 and 5,780 shares of common stock, respectively, at cost	(445,317)	(23,840)
Unearned compensation	(522,680)	(976,547)
Total shareholders' equity	52,764,614	64,727,641
	$ 67,519,442	$ 82,910,607

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2002	2001	2000
Net sales	$ 69,029,866	$69,908,296	$ 6,529,581
Cost of sales	27,312,811	19,164,436	4,257,602
Impairment and related charges	6,900,000	—	—
Gross margin	34,817,055	50,743,860	2,271,979
Operating expenses:			
Research and development	13,299,677	12,756,257	17,118,976
Sales and marketing	26,874,945	34,653,392	15,650,756
General and administrative	8,334,928	9,324,347	6,321,186
Restructuring and other expense	—	1,213,705	—
Total operating expenses	48,509,550	57,947,701	39,090,918
Loss from operations	(13,692,495)	(7,203,841)	(36,818,939)
Interest income	747,318	2,164,295	3,784,378
Interest expense	(105,734)	(75,783)	(22,535)
Other income (expense)	—	6,488	(16,377)
Total other income	641,584	2,095,000	3,745,466
Net loss	$(13,050,911)	$ (5,108,841)	$(33,073,473)
Net loss per share—basic and diluted	$ (0.80)	$ (0.32)	$ (2.13)
Weighted average shares outstanding-basic and diluted	16,268,329	16,152,360	15,517,272

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		Unearned Compensation	Total
	Shares	Amount				Shares	Amount		
Balance at December 31, 1999	14,201,632	$142,016	$128,182,542	$ 57,722	$ (83,201,214)	(5,780)	$(23,840)	$(2,092,382)	$43,064,844
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	—	—	—	—	—	48,697,225
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	—	—	—	—	(105,375)	—
Cancellation of unvested equity awards issued to officer	(7,500)	(75)	(249,300)	—	—	—	—	249,375	—
Other equity transactions	—	—	114,880	—	—	—	—	—	114,880
Amortization of unearned compensation	—	—	—	—	—	—	—	710,162	710,162
Deferred consulting charges on stock option grants	—	—	328,876	—	—	—	—	—	328,876
Exercise of stock options at $1.00 to $29.63 per share	426,544	4,265	7,141,874	—	—	—	—	—	7,146,139
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	—	—	—	—	—	204,878
Comprehensive loss:									
Translation adjustment	—	—	—	(151,412)	—	—	—	—	(151,412)
Net loss	—	—	—	—	(33,073,473)	—	—	—	(33,073,473)
Total comprehensive loss	—	—	—	—	—	—	—	—	(33,224,885)
Balance at December 31, 2000	16,094,635	$160,946	$184,511,610	$ (93,690)	$(116,274,687)	(5,780)	$(23,840)	$(1,238,220)	$67,042,119

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		Unearned Compensation	Total
	Shares	Amount				Shares	Amount		
Exercise of stock options at $3.20 to $27.00	117,188	1,172	1,258,302	—	—	—	—	—	1,259,474
Deferred compensation relating to issuance of stock options to officers	—	—	839,361	—	—	—	—	(594,547)	244,814
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	—	—	—	—	—	638,224
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	—	—	—	—	(92,080)	—
Amortization of unearned compensation								948,300	948,300
Other equity transactions	—	—	18,000	—	—	—	—	—	18,000
Comprehensive loss:									
Translation adjustment:	—	—	—	(314,449)	—	—	—	—	(314,449)
Net loss	—	—	—	—	(5,108,841)	—	—	—	(5,108,841)
Total Comprehensive loss	—	—	—	—	—	—	—	—	(5,423,290)
Balance at December 31, 2001	16,265,081	$162,651	$187,357,044	$(408,139)	$(121,383,528)	(5,780)	$(23,840)	$(976,547)	$64,727,641

See accompanying notes.

NOVOSTE CORPORATION
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock		Add'l Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock		Unearned Compensation	Total
	Shares	Amount				Shares	Amount		
Exercise of stock options $1.00 to $6.65	61,375	614	336,751	—	—	26,150	110,685	—	448,050
Deferred compensation relating to issuance of stock options	—	—	364,816	—	—	—	—	(364,816)	—
Issuance of stock under Employee Stock Purchase Plan, 25,497 shares at $4.08 and 21,353 shares at $3.927	25,497	255	103,759	—	—	21,353	83,868	—	187,882
Amortization of unearned compensation	—	—	—	—	—	—	—	272,883	272,883
Stock-repurchase	—	—	—	—	—	(159,800)	(616,030)	—	(616,030)
Compensation expense relating to accelerated vesting of stock options to a former officer	—	—	196,873	—	—	—	—	—	196,873
Cancellation of unvested equity awards issued to officers	—	—	(545,800)	—	—	—	—	545,800	—
Comprehensive income (loss):									
Unrealized loss on short-term investments	—	—	—	(19,468)	—	—	—	—	(19,468)
Translation adjustment	—	—	—	617,694	—	—	—	—	617,694
Net loss	—	—	—	—	(13,050,911)	—	—	—	(13,050,911)
Total comprehensive loss	—	—	—	—	—	—	—	—	(12,452,685)
Balance at December 31, 2002	16,351,953	$163,520	$187,813,442	$190,087	$(134,434,438)	(118,077)	(445,317)	$(522,680)	$52,764,614

See accompanying notes.

NOVOSTE CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	2002	2001	2000
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$(13,050,911)	$ (5,108,841)	$(33,073,473)
Adjustments to reconcile net loss to net cash provided (used) by operating activities:			
Depreciation and amortization of property and equipment	3,125,499	2,413,135	1,458,994
Amortization of radiation and transfer devices	9,240,887	5,087,576	131,815
Issuance of stock for services or compensation	—	244,814	328,876
Amortization of deferred compensation	469,756	948,300	710,162
Provision for doubtful accounts	288,227	590,814	305,633
Unrealized loss on short-term securities	(19,468)	—	—
Impairment charge	5,065,000	—	—
Change in assets and liabilities:			
Accounts receivable	9,325,631	(12,410,361)	(3,871,403)
Inventory	(85,396)	(2,585,997)	1,144,159
Prepaid expenses and other current assets	36,294	(541,035)	(265,502)
Accounts payable	(2,032,948)	644,186	2,422,905
Accrued expenses and taxes withheld	(1,000,948)	5,535,613	250,908
Unearned revenue	(387,268)	2,216,210	577,881
Other	(265,402)	(465,609)	(404,572)
Net cash provided (used) by operations	10,708,953	(3,431,195)	(30,283,617)
CASH FLOWS FROM INVESTING ACTIVITIES			
Maturities (purchase) of short-term investments, net	20,036,830	(1,028,191)	3,677,230
Purchase of property and equipment	(2,729,730)	(4,920,879)	(4,564,549)
Purchase of radiation and transfer devices	(12,124,342)	(13,140,984)	(5,612,763)
Net cash provided (used) by investing activities	5,182,758	(19,090,054)	(6,500,082)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock	635,932	1,915,698	56,163,122
Purchase of treasury stock	(616,030)	—	—
Payments on capital lease obligations	(269,695)	(261,918)	(52,248)
Net cash provided (used) by financing activities	(249,793)	1,653,780	56,110,874
Effect of exchange rate changes on cash	408,258	233,357	94,198
Net increase (decrease) in cash and cash equivalents	16,050,176	(20,634,112)	19,421,373
Cash and cash equivalents at beginning of period	5,878,286	26,512,398	7,091,025
Cash and cash equivalents at end of period	$ 21,928,462	$ 5,878,286	$ 26,512,398
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid for interest	$ 105,734	$ 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 commenced operations on May 22, 1992. The Company is a medical device company that is engaged in commercializing the Beta-Cath™ System, an intraluminal beta radiation catheter delivery system designed to reduce restenosis subsequent to percutaneous transluminal coronary angioplasty. In addition, the Company is investigating the use of the Beta-Cath™ System in peripheral vascular applications. In the course of its development activities the Company has sustained operating losses through December 31, 2002.

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™ 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™ 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 August 1998 in the Netherlands, in December 1998 in Belgium, in February 1999 in Germany, in January 2000 in France and a dedicated sales corporation incorporated in the state of Florida in July, 2002. Significant inter-company transactions and accounts have been eliminated.

On August 19, 2002, the Company initiated a voluntary recall of the Beta-Rail™ 3.5F Delivery Catheter inventory from its customers. The recall related to the discovery by the Company of a small number of catheter-tip separations in the 3.5F product. An extensive evaluation and improvement program was initiated. A pre-market approval supplement was submitted to the Food and Drug Administration ("FDA") on October 15, 2002, defining the improvements to the product and manufacturing processes and requesting approval for re-launch of the product. The FDA approved the re-launch on January 6, 2003.

The impact of the 3.5F catheter recall has been included in the consolidated financial statements of the Company and is recorded in the corresponding revenue and expense categories as appropriate, based upon the nature of the expense or adjustment. During the third quarter of 2002, net sales were adjusted by approximately $3.3 million for 3.5F catheters that were sold to customers but subsequently returned due to the recall. Cost of sales reflects approximately $800,000 for the disposal of existing 3.5F catheters in inventory and for the additional labor and costs in shipping 5.0F replacement transfer devices, radiation source trains and catheters to our customers. Operating expenses reflect the labor and material costs involved in testing the 3.5F catheters in order to determine the proper corrective actions to be included in our reports to the FDA.

In the opinion of management, all adjustments (consisting of normal recurring accruals and estimated write-downs and accruals resulting from the recall) considered necessary for a fair presentation of Novoste's financial results and condition have been recorded.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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™ 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™ 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.

Sales are final and revenue is recorded at time of shipment. Product is not returnable except for shipping errors or warranty claims. An estimate of $78,000 for such returns is recorded as a reduction to net sales and included in accrued liabilities. In addition, due to the pending re-launch of the 3.5F diameter catheter, the Company recorded a reserve of $2,150,000 for anticipated exchanges which is recorded as a reduction to net sales and included in deferred revenue. The Company intends to allow customers who previously utilized the 3.5F Beta-Cath™ System prior to the recall to exchange 5.0F catheters once the appropriate training has been performed. Additionally, from time to time the Company offers opportunities for customers to earn allowances through promotional activities such as reaching quantity milestones. An estimate of $86,000 for promotional allowances is recorded as a reduction to net sales and included in accrued liabilities. At December 31, 2001, the total accrual for returns and allowances was approximately $100,000.

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 their estimated useful life. (See Radiation and Transfer Devices)

Beginning in the fourth quarter of 2000 and in subsequent years, 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 at the lower of revenue earned based on actual catheters purchased or on a straight-line basis over the term of the related agreements, if collection is considered probable. Costs are recorded over the estimated useful life of the radiation source train and transfer device.

During 2002, 2001 and 2000, approximately $4,547,000, $6,814,000 and $365,000 respectively, of net sales related to the lease of radiation transfer devices were recorded.

Accounts Receivable

Accounts receivable at December 31, 2002 and 2001 include 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.

There were no significant concentrations of credit risk in 2002 or 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, 2002, 2001 and 2000 amounted to $372,000, $598,000 $311,000 respectively. For December 31, 2002, 2001 and 2000, un-collectible accounts written off totaled $246,000, $23,000 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 and also provides an advance for related payroll taxes. The payroll tax advance is reflected as a receivable from officers on the balance sheet. The advances are unsecured and are subject to the life insurance company's ability to repay the Company in the future from the available funds. 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, the life insurance company is obligated to repay the Company for the tax advances prior to settlement of the account with the officer. At December 31, 2002 and 2001, the receivable from officers balance was $282,429 and $144,025, respectively.

The Company has ceased accepting further contributions to the plan from Executive Officers. Several officers have withdrawn from the plan and $163,143 of the outstanding balance was refunded to the Company in January 2003.

Advertising Costs

All advertising costs are expensed as incurred. Approximately $838,000, $1,350,000 and $1,155,000 were charged to advertising expense for the years ended December 31, 2002, 2001 and 2000, 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 3,590,016, 3,506,144 and 2,483,157 related primarily to stock options are not included in the per share calculations for 2002, 2001 and 2000, respectively, as the effect of their inclusion would be anti-dilutive.

Cash Equivalents and Short-term Investments

Cash equivalents are comprised of certain highly liquid investments with maturities of less than three months at the time of their acquisition. In addition to cash equivalents, the Company has investments in commercial paper and other securities that are classified as short-term. Management determines the appropriate classification of debt securities at the time of purchase.

All securities are considered as available-for-sale and reported at fair value, with the unrealized gains and losses reported as a component of Other Comprehensive Income (Loss) on the Consolidated Statement of Shareholders' Equity. The amortized cost of debt securities in this category, if significant, is adjusted for amortization included in interest income but are nominal. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, of which there were none, would be included in other income. Realized gains and losses are included in interest income and are determined on a specific identification basis. Interest and dividends on securities classified as available-for-sale are included in interest income.

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 6%, 7% and 74% of total revenues for the years ended December 31, 2002, 2001 and 2000, respectively. The Company experienced an immaterial amount of transaction gains and losses in 2002 and 2001 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. Foreign exchange rate fluctuations, during 2002, 2001 and 2000 are reflected in Other Comprehensive Income (Loss) on the Consolidated Statement of Shareholders' Equity. During 2002, the Euro appreciated against the dollar approximately 18 percent, resulting in approximately $600,000 of Other Comprehensive Income.

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, 2002	December 31, 2001
Raw Materials	$2,877,997	$1,971,347
Work in Process	201,869	811,406
Finished Goods	847,013	963,680
Total	$3,926,879	$3,746,433

Inventory reserves increased from $15,000 at December 31, 2001 to 844,000 at December 31, 2002. The increase is due mainly to product which was part of the voluntary recall.

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, 2002	December 31, 2001
Furniture and Fixtures	$ 1,413,276	$ 1,358,180
Office Equipment	5,292,590	4,759,623
Laboratory Equipment	1,007,420	732,818
Leasehold Improvements	2,213,114	2,131,813
Production Equipment	8,472,118	7,119,161
	18,398,518	16,101,595
Less: Accumulated Depreciation and Amortization	(8,856,716)	(6,214,884)
	$ 9,541,802	$ 9,886,711

Long-lived Assets

In accordance with Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, long-lived assets are reviewed for impairment whenever events indicate that their carrying amount may not be recoverable. In such reviews, estimated discounted future cash flows associated with these assets are compared with their carrying value to determine if a write-down to fair value is required (Note 8).

Radiation and Transfer Devices

The Company retains ownership of the radiation source trains (RSTs) and transfer devices (TDs). Depreciation of the costs of these assets is taken over the estimated useful life using the straight-line method and is recorded in Cost of Sales. Depreciation begins at the time the Beta-Cath™ System is placed into service. The annual agreements with the Company's customers to license the use of radiation and transfer devices are classified by the Company as operating leases. Income is recognized ratably over the length of the lease. During 2002, the Company's pricing policy for leases changed as an accommodation to customers. Many of the second year leases were renewed at no additional costs to the customer based on individual customer pricing decisions. At December 31, 2002, deferred revenue under leases approximated $.3 million.

During 2001, the Company estimated the useful lives of these assets to be eighteen months based upon the information available at that time. During January 2002, the Company determined that, based upon new testing and experience, the estimated useful lives of RSTs was twelve months and the TDs was three years. Accordingly, depreciation has been recorded over the new estimated lives starting at the beginning of the first quarter 2002. The Company begins depreciation when the Beta-Cath™ system is placed into service.

In June 2002, the Company decided to concentrate marketing and product development efforts on the 3.5F diameter Beta-Cath system. An impairment charge of $5.1 million was recognized in the second quarter for the estimated fair value of the 5.0F diameter system (Note 8). Depreciation on the remaining fair value of the 5.0F assets (after the impairment charge) has been accelerated and is being recorded over the expected remaining useful commercial life, which extends through March 31, 2003. Fair value was determined by reviewing the estimated future cash flows associated with 5.0F assets compared to the carrying value of these assets in accordance with SFAS 144 (Note 8).

The impact of the change in estimate of useful lives in 2002 is as follows:

Change	Increase (Decrease) Cost of sales
Change in radiation devices life from 18 months to 12 months (RST's) and 36 months (TD's)	$(3,838,000)
Impairment of $5,065,000 and other related charges of $1,800,000 on 30mm and 40mm 5.0F RST's and TD's (Note 8)	6,865,000
Acceleration of useful lives of 30mm, 40mm and 60mm 5.0F RST's and TD's	612,000
Net impact in 2002	$ 3,639,000
Net effect on loss per share in 2002	$ (0.22)

The result of this change is that amortization for existing assets at December 31, 2002, will be less in future periods due to the impairment charges and accelerated amortization of 5.0F assets, offset by longer lives for other radiation devices.

At December 31, 2002, equipment with a cost of approximately $31.0 million, less $5.1 million reserve for impairment (See Note 8) before accumulated depreciation and reserves of approximately $14.6 million, was

subject to operating leases. Obsolescence reserves of $937,000 and $895,000 for 2002 and 2001, respectively, are included with depreciation due to their non-cash nature. Radiation and transfer devices are stated at cost and are comprised of the following

	December 31, 2002	December 31, 2001
Radiation and Transfer Devices	$ 31,004,602	$19,649,069
Less: Impairment	(5,065,000)	—
Net Radiation and Transfer Devices	25,939,602	19,649,069
Less: Accumulated Depreciation	(14,586,801)	(6,114,713)
	$ 11,352,801	$13,534,356

Approximately $2.2 million of radiation and transfer devices were available for lease at December 31, 2002.

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 sets forth accounting and reporting standards for stock-based employee compensation plans (Note 9). As permitted by SFAS 123, the Company accounts for stock option grants in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees 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.

In December 2002, the FASB issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. SFAS 148 amends Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method on reported results.

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 2002, 2001 and 2000: 10-year treasury bill interest rates of 4.24%, 4.22% and 5.66%, respectively; no dividend yields; volatility factor of the

expected market price of the Company's common stock of 1.24, 1.29 and 1.29, in 2002, 2001 and 2000, respectively; and a weighted-average expected life of the option of five years for 2002, and 2001 and 2000.

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.

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.

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,		
	2002	2001	2000
Net loss, as reported	$(13,050,911)	$ (5,108,841)	$(33,073,473)
Add: Total stock-based employee compensation expense included in net loss	469,756	948,300	710,162
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(7,006,064)	(13,497,824)	(8,651,205)
Pro forma net loss	$(19,587,219)	$(17,658,365)	$(41,014,516)
Earnings per share:			
Basic-as reported	$ (0.80)	$ (0.32)	$ (2.13)
Basic-pro forma	$ (1.20)	$ (1.09)	$ (2.64)
Dilutive-as reported	$ (0.80)	$ (0.32)	$ (2.13)
Diluted-pro forma	$ (1.20)	$ (1.09)	$ (2.64)

New Accounting Pronouncements

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 2002, the FASB issued Statement of Financial Accounting Standards No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 requires that a liability for costs associated with an exit or disposal activity be recognized and measured initially at fair value only when the liability is incurred. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002 and is not expected to have a material effect on the financial statements of Novoste.

In November 2002, the FASB issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees. FIN 45 requires a guarantor to recognize, at the inception of a guarantee, a liability for the fair value of the obligation it has undertaken in issuing the guarantee. The Company will apply FIN 45 to guarantees, if any, issued after December 31, 2002. At adoption, FIN 45 did not have a significant impact on the

Company's consolidated statements of operations or financial position. FIN 45 also requires guarantors to disclose certain information for guarantees, including product warranties, outstanding at December 31, 2002.

In November 2002, the EITF reached a consensus on EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The Issue addresses certain aspects of the accounting for arrangements under which a vendor will perform multiple revenue-generating activities. EITF 00-21 addresses when a revenue arrangement with multiple deliverables should be divided into separate units of accounting and, if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. The Company is required to adopt the provisions of EITF 00-21 effective July 1, 2003, and the Company does not expect the adoption of EITF 00-21 to have a material impact on its results of operations or financial condition.

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 2002, 2001, and 2000 approximately, $0, $20,000 and $399,000, 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 equipment. Rent expense was approximately $676,700, $956,000 and $707,000 for 2002, 2001 and 2000, respectively. The total future minimum rental payments are as follows:

2003	$ 901,000
2004	848,500
2005	775,000
	$2,524,500

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™ System (excluding consideration paid for the radioactive isotope), subject to a maximum payment of $5,000,000. Royalty fees to the physician aggregated, $667,540, $632,300 and $63,200 in 2002, 2001 and 2000 and have been expensed in cost of sales. Approximately $3,600,000 remains to be paid.

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, $1,377,579, $1,443,967 and $146,050 in 2002, 2001 and 2000 and have been expensed in cost of sales.

During 2000, the Company obtained all of its requirements of radiation source materials (totaling $1,487,000) pursuant to an agreement, as amended (the "Supply Agreement"), with a single German supplier, Bebig Isotopentechnik and Umweltdiagnostik GmbH. In 2002 and 2001, the Company purchased radiation source materials from two suppliers, Bebig Isotopentechnik und Umweltdiagnostik GmbH ($4,161,000 and $2,438,000, respectively) and AEA Technologies QSA, GmbH ($5,046,000 and $1,115,000, respectively). At December 31, 2002 and 2001, the Company had commitments to purchase approximately $4,409,000 and $7,185,000 respectively, of various inventory components for the Beta-Cath™ System. At December 31, 2002, approximately $1,800,000 of the purchase commitments has been expensed in cost of sales.

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 disposal requirements for isotopes and has contracted with third parties to handle this disposal. The Company has also accrued $250,000 for the isotope equipment disposal which is recorded in accrued expenses. In addition, the Company has accrued $319,000 for isotope seed disposal at December 31, 2002 which is recorded in accrued expenses and radiation and transfer devices, net. The amount is recorded as a cost of acquiring the radiation source train asset and is amortized over its useful life.

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, 2002, 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 obtained a $10 million revolving line of credit. During the twelve months ended December 31, 2002 the Company had borrowed $4 million against the line of credit; however, at December 31, 2002 and December 31, 2001, the Company had no outstanding borrowings. The Company may borrow an amount not to exceed the borrowing base as defined in the loan agreement, which is principally based on domestic accounts receivables. Interest on outstanding balances 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%. The Company granted a first priority security interest in substantially all assets of the Company to the lender. At December 31, 2002 the Company was in violation of the tangible net worth covenant of its revolving loan agreement; the lender has issued a waiver for that violation through February 28, 2003. By agreement between the Company and the lender, the maturity date of the original Loan Agreement between the parties had been extended to February 28, 2003, and by further agreement, the maturity date has been extended to February 27, 2004. Also as part of that modification, the tangible net worth covenant was changed, bringing the Company into compliance, and the interest rate was changed to a base of the greater of the bank's prime rate or 4.25%, plus 1%.

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

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, 2002	December 31, 2001
Deferred Income Tax Assets:		
Net operating loss carryforwards	$ 50,684,368	$ 48,334,941
R&D tax credit carryforwards	2,432,065	1,481,225
Provision for doubtful accounts	57,000	57,000
Other	2,811	—
Accruals/reserves	4,153,479	1,436,791
Property and Equipment	396,452	935,714
Deferred compensation	—	360,352
	57,726,175	52,606,023
Valuation allowance for Deferred Income Tax assets	(57,726,175)	(52,606,023)
Net Deferred Income Tax Assets	$ —	$ —

At December 31, 2002 and 2001, 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 2002, 2001, or 2000. The Company has approximately $119.5 million of net operating losses for U.S. federal income tax purposes available to offset future taxable income. Such losses expire in 2007 through 2022 and may be subject to annual limitations on usage due to changes in ownership. Net operating loss carry forwards aggregating approximately $13.5 million representing cumulative exercises of non-qualified stock options will result in a credit to contributed capital when recognized. The activity in the valuation allowance includes the tax effect of these non-qualified stock options. The Company has approximately $13.9 million of foreign net operating losses related to its European subsidiaries. Additionally, the Company has approximately $2.4 million in research and development tax credits that expire in 2008 through 2022 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:

	2002	2001	2000
Tax benefit at statutory	$(4,437,310)	$(1,737,006)	$(11,244,981)
State tax, net of federal benefit	(481,360)	(203,679)	(1,322,939)
R&D tax credit	(925,351)	(441,262)	(501,561)
Other	345,753	577,019	61,027
Valuation allowance for deferred income tax	5,498,268	1,804,928	13,008,454
	$ —	$ —	$ —

6. SHORT-TERM INVESTMENTS

At December 31, 2002 and 2001, short-term investments consist of debt securities classified as available-for-sale. 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, 2002, 2001 and 2000.

Available-for-Sale Investments

Available-for-sale investments at December 31, 2002 were as follows:

	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Loss	Estimated Fair Value
Money market	$ 9,240,000	$ —	$ —	$ 9,240,000
Commercial paper	8,676,000	—	—	8,676,000
Asset backed bonds	4,750,000	—	(26,000)	4,724,000
Corporate bonds	4,166,000	6,000	—	4,172,000
Government bonds	1,003,000	1,000	—	1,004,000
Total available for sale investments	27,835,000	$7,000	$(26,000)	$27,816,000
Less amounts classified as cash equivalents	(16,169,000)			
Unrecognized net loss	(19,000)			
	$ 11,647,000			

Available-for-sale investments at December 31, 2001 were as follows:

	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Loss	Estimated Fair Value
Money market	$14,494,000	$ —	$ —	$14,494,000
Commercial paper	1,494,000	—	—	1,494,000
Asset backed bonds	5,098,000	—	—	5,098,000
Corporate bonds	10,598,000	—	—	10,598,000
Government bonds	—	—	—	—
Total available for sale investments	$31,684,000	$ —	$ —	$31,684,000
Less amounts classified as cash equivalents	—			
Unrecognized net loss	—			
	$31,684,000			

The amortized cost and estimated fair value of available-for-sale investments in debt securities at December 31, 2002, by contractual maturity, were as follows:

	Adjusted Cost	Estimated Fair Value
Due in 1 year or less	$23,085,000	$23,092,000
Due in 1-2 years	2,720,000	2,701,000
Due in 2-5 years	2,030,000	2,023,000

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, 2002, lease payments under capital leases were $303,399. Amortization of assets recorded under capital leases is included in depreciation expense.

Future minimum lease payments under capital leases are as follows:

2003	$192,407
2004	5,333
2005	0
	$197,740
Less amounts representing interest	15,088
	$182,652

8. RESTRUCTURING CHARGES, IMPAIRMENT 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 the balance in 2002. The Brussels office closed in March 2002.

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

Impairment and related charges of $6.9 million were recorded in 2002 related to the Company's decision to concentrate marketing and development efforts on the new 3.5F diameter Beta Cath System. The Company evaluated the recoverable value of the 5.0F systems that are equipped to use with 30mm and 40mm radiation source trains. Based on this evaluation, the Company determined that the 5.0F transfer devices and the related radiation source trains, which are long-lived assets, with a carrying amount of $8.6 million, were impaired and wrote them down by $5.1 million to their estimated fair value of $3.5 million, and accrued $1.8 million for related contract commitments, resulting in impairment and other related charges of $6.9 million for the second quarter of 2002. Fair value was based on expected future net cash flows to be generated by the transfer devices and radiation source trains during their remaining service lives, discounted at the risk-free rate of interest. The remaining fair value is amortized ratably over the estimated useful life of these assets which extends through March 31, 2003. At December 31, 2002 the net book value of 5.0F impaired assets was $1.4 million.

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 or group has acquired at least 15% of the Company's Common Stock. 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. Each Right, should it become exercisable, will entitle the owner to buy 1 1/100th (0.01) of a share of new Series A participating preferred stock at an exercise price of $85.

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 or group 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 group) 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 this 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 at the time of grant and may be exercised for a period of ten years from the grant date. 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 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 at the time of grant and may be exercised for a period of ten years from the grant date. 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 control as defined in the incentive and non-qualified stock option agreements.

Effective February 12, 2002, the Company's Board of Directors adopted the Novoste Corporation 2002 Broad-Based Stock Plan (the "Plan"), which makes 200,000 shares available for grant to employees, officers, consultants, independent contractors or non-employee directors providing services to the Company or affiliates. The Plan limits the number of shares that may be granted to officers and directors to 100,000 shares. The Plan permits the granting of options, stock appreciation rights, restricted stock, restricted stock units, performance awards, other stock grants and other stock-based awards. Furthermore, awards other than options are limited to 10% of the total number of shares authorized and the purchase price per share of options may not be less than the fair market value on grant date. The Plan authorizes the committee designated by the Company's Board of Directors to set the term and to accelerate the exercisability of awards. Under the Plan, 180,800 shares were granted, 24,400 shares were cancelled and 43,600 shares remain available for grant in year 2003.

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

	Number Of Shares	Price Per Share	Weighted Average Price
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	1,425,350	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
Options granted	1,413,274	3.700-8.100	4.86
Options exercised	(87,525)	1.000-6.650	5.12
Options forfeited	(1,240,266)	3.700-49.250	22.54
Outstanding at December 31, 2002	3,586,041	3.200-49.250	11.14
Exercisable at December 31, 2002	1,632,212	$ 3.200-49.250	$13.82

At December 31, 2002 the Company has 3,771,916 shares of common stock reserved for issuances under these employee and director stock option arrangements and 146,883 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	955,700	9.67	$ 4.16	140,000	$ 4.11
5.01– 7.00	1,219,750	9.03	6.52	568,896	6.61
7.01– 10.50	130,500	9.11	7.86	57,150	7.71
10.51– 13.38	244,947	6.08	11.77	228,322	11.83
13.39– 21.94	338,200	6.25	16.73	195,785	17.42
21.95– 22.50	269,589	7.76	22.50	139,451	22.50
22.51– 24.69	153,400	5.95	23.86	125,600	23.97
24.70– 49.25	273,955	6.27	31.81	177,008	31.16
	3,586,041	8.30	$11.14	1,632,212	$13.82

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: $126,564, $415,035 and $429,220 were expensed in 2002, 2001 and 2000, respectively. Approximately 37,500 of these options awarded to a former officer of the Company were forfeited during 2000, reducing the incurred compensation by $72,656 to $1,719,844.

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 $839,361, 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 $209,840 and $344,800 were expensed in 2002 and 2001 respectively, relating to these options.

In July 2002 the Company accelerated the vesting of options to a former senior officer serving on the board as part of his separation compensation. The Company recorded compensation expense of $196,873 as a result of this acceleration.

In May 2002 certain executive officers voluntarily surrendered options for 713,750 shares, most of which were exercisable at prices in excess of $20.10 per share. By surrendering the options these officers were not eligible to receive any options for more than six months.

In November 2002, the Company issued 19,375 shares to an officer of the Company as a replacement award to previously canceled options. The Company recorded $91,200 in compensation expense associated with the issuance of these awards.

The weighted-average fair value of options granted during 2002 is $4.14.

During 2002, 2001, and 2000, 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, 2002, 44,975 of these restricted shares have vested. The remaining 3,975 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 $55,119, $433,538 and $280,943 in 2002, 2001 and 2000, respectively. The value of the remaining shares awarded totaled $82,858 at December 31, 2002 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 2002, 2001 and 2000 the Company matched 33⅓% of the first 6% of employee contributions, aggregating $293,000, $239,000 and $124,000, respectively.

Effective July 1, 2000, the Company adopted an Employee Stock Purchase Plan ("Plan"), which makes available up to 250,000 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, 2002, 103,117 shares have been purchased under the Plan.

11. RELATED PARTY TRANSACTIONS

On December 23, 2002, the Company signed a Distribution Agreement with Orbus Medical Technologies, Inc., a manufacturer of cardiology products. The Company's Chief Executive Officer, Mr. Al Novak is also the Chairman of Orbus Medical Technologies, Inc. As of December 31, 2002, the Company has prepaid $250,000 for future product inventory.

12. SEGMENT INFORMATION

SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information 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, long-lived assets and total assets by geographic area are as follows:

Net sales	United States	Europe	Rest of World	Consolidated
2002	$ 64,746,263	$ 3,815,499	$ 468,104	$ 69,029,866
2001	64,696,793	4,576,114	635,389	69,908,296
2000	1,816,250	4,224,776	488,555	6,529,581

Net Loss	United States	Europe	Rest of World	Consolidated
2002	$ (8,108,949)	$(4,253,159)	$(688,803)	$(13,050,911)
2001	2,953,210	(7,524,276)	(537,775)	(5,108,841)
2000	(27,683,138)	(5,235,572)	(154,763)	(33,073,473)

Long-lived assets	United States	Europe	Rest of World	Consolidated
2002	$ 18,303,608	$ 2,452,071	$ 138,924	$ 20,894,603
2001	22,539,628	723,329	158,110	23,421,067

Total assets	United States	Europe	Rest of World	Consolidated
2002	$ 62,615,378	$ 4,673,377	$ 230,687	$ 67,519,442
2001	76,718,408	5,869,865	322,334	82,910,607

At December 31, 2002 and 2001, the Company's net assets outside of the United States, consisting principally of cash and cash equivalents, accounts receivable, inventory and office equipment, were approximately $4,904,000 and $6,192,000, respectively.

13. SUBSEQUENT EVENTS

On January 6, 2003, the FDA approved the re-launch of a redesigned 3.5F diameter Beta Rail catheter. On March 4, 2003, the Company signed an agreement extending the maturity date of its revolving loan to February 27, 2004.

14. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Fiscal 2002	First Quarter Ended March 31	Second Quarter Ended June 30	Third Quarter Ended September 30	Fourth Quarter Ended December 31
Net sales and revenue	$22,932,352	$16,824,300	$14,655,449	$14,617,765
Cost of sales	6,678,121	6,214,300	6,774,235	7,646,155
Impairment and related charges	0	6,900,000	0	0
Gross Margin	16,254,231	3,710,000	7,881,214	6,971,610
Income (loss) from operations	3,179,785	(8,592,358)	(3,380,660)	(4,899,262)
Net income (loss)	3,402,492	(8,551,494)	(3,286,874)	(4,615,035)
Net income (loss) per share	0.21	(0.52)	(0.20)	(0.29)

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

The Company recorded impairment and related charges of $6.9 million in the second quarter of 2002 and a restructuring charge and other expense in the amount of $1.2 million during the fourth quarter ended December 31, 2001. Quarterly net income (loss) per share amounts do not agree to full year net income (loss) per share amounts because of the dilutive effect of options outstanding on profitable quarters.

INDEX TO EXHIBITS

Exhibit Numbers	Description
3.1	Amended and Restated Articles of Incorporation of Registrant filed on May 28, 1996. (16)
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, 1996. (2)
3.3(a)	Copy of Amended and Restated By-Laws of Registrant adopted December 20, 1996. (15)
3.3(b)	First Amendment to the Second Amended and Restated By-Laws dated October 16, 2002.
4.1	Form of Specimen Common Stock Certificate of Registrant. (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 thereto 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 Corporation 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, with 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 the purchase of assets of Registrant's supplier of radioactive beta isotopes. (1)
H10.10	Frame Agreement with Bebig Isotopentechnik und Umweltdiagnostik GmbH regarding purchases and investment grant. (15)
*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. dated February 11, 2000 (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 SeaMED, a Plexus Company. (11)
*10.22	Restricted Stock Award dated July 1, 1999 between Novoste Corporation and William A. Hawkins. (9)
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)

Exhibit Numbers	Description
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)
10.34	Employment Agreement with Alfred Novak dated October 8, 2002. (16)
10.35	Non-Qualified Stock Option Agreement with Chief Executive Officer dated October 16, 2002. (16)
10.36	Non-Qualified Stock Option Agreement with Chief Executive Officer dated October 16, 2002. (16)
10.37	2002 Chief Executive Officer Stock Option Plan. (16)
21.	Subsidiaries of Novoste Corporation. (16)
23.1	Consent of Ernst & Young LLP, Independent Auditors
99.1	Statements of Alfred J. Novak, Chief Executive Officer, and Edwin B. Cordell, Jr. Chief Financial Officer, pursuant to 18 U.S.C. Section 1350.

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 filed on November 5, 1996.

(3) Filed as Exhibit A to the Registrant's Proxy Statement for its 1999 Annual Meeting of Stockholders filed on April 12, 1999.

(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, 2002.

(14) Filed as Exhibit 99.1 to the Registrant's Report on Form 8-K filed October 17, 2002.

(15) Filed as same numbered Exhibit to the Registrant's Report on Form 10-K filed on March 10, 1997.

(16) Filed as same numbered Exhibit to the Registrant's Report on Form 10-K filed on March 31, 2003.

* Constitutes a compensatory plan, contract or arrangement.

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Headquarters
Novoste Corporation
3890 Steve Reynolds Boulevard
Norcross, Georgia 30093
(770) 717-0904
(770) 717-1455 fax

International Office
Novoste Europe GmbH
Hüttennallee 237c
47800 Krefeld
Germany
+49 2151 50732 0
+49 2151 50732 50 fax

Transfer Agent
American Stock Transfer & Trust Company
6201 15th Avenue
Brooklyn, New York 11219
(718) 921-8293

Independent Auditors
Ernst & Young LLP
Atlanta, Georgia

Legal Counsel
Hogan & Hartson LLP
New York, New York

Annual Meeting
The annual meeting for shareholders will take place on June 10, 2003 beginning at 8:30 a.m. at the Atlanta Marriott Norcross, 475 Technology Parkway, Norcross, Georgia.

Investor Information Requests
Copies of the Company's Annual Report and Form 10-K may be obtained without charge upon written request to:

Novoste Corporation
Investor Relations
3890 Steve Reynolds Boulevard
Norcross, Georgia 30093

Investor relations may also be contacted through our website, www.novoste.com.

Stock Listing and Stock Price History
The Company's Common Stock is traded on the Nasdaq National Market (Nasdaq symbol: NOVT). The number of record holders of the Company's Common Stock at March 14, 2003 was 99, 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 Note 9 of the Notes to the Consolidated Financial Statements in the Novoste Corporation Form 10-K, and does not intend to pay any dividends in the foreseeable future.

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

Quarter ended	High	Low
March 31, 2002	**$ 11.27**	**$ 6.55**
June 30, 2002	**8.66**	**4.65**
September 30, 2002	**5.05**	**3.35**
December 31, 2002	**7.07**	**3.97**
March 31, 2001	$ 38.87	$ 14.00
June 30, 2001	25.50	13.62
September 30, 2001	25.25	6.05
December 31, 2001	13.31	5.73

On March 14, 2003, the last reported sale price for the Common Stock was $7.95.

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Novoste Corporation
3890 Steve Reynolds Boulevard
Norcross, Georgia 30093
(770) 717-0904
www.novoste.com

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