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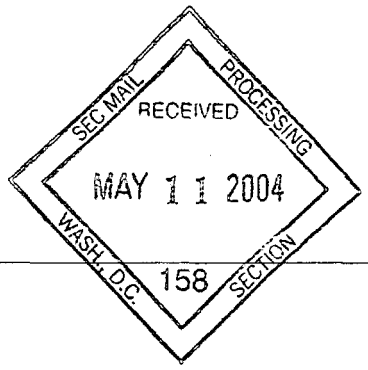


NOVOSTE CORPORATION

2003 Annual Report

Novoste Corporation is the world leader in the field of vascular brachytherapy (VBT) – radiation therapy delivered inside an artery to prevent it from re-closing (restenosis). Restenosis occurs when scar tissue grows inside an artery and limits blood flow after procedures such as angioplasty, often resulting in the need for additional procedures to re-open the vessel. The Company's Beta-Cath™ System received marketing approval from the U.S. Food and Drug Administration (FDA) in November, 2000. The Beta-Cath™ System was the first commercially available vascular brachytherapy device in both the United States and Europe. To date, over 75,000 patients have been treated worldwide with the Novoste™ Beta-Cath™ System.

The Beta-Cath™ System was approved by the FDA for use in 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. Before vascular brachytherapy, there were no effective treatments for in-stent restenosis other than bypass surgery, an expensive and highly invasive procedure.

AFTER A YEAR THAT FOUND NOVOSTE CORPORATION CONFRONTING SEVERAL CRITICAL CHALLENGES AND REDEFINING ITS MOST REASONABLE FORWARD-LOOKING STRATEGIES, NOVOSTE PRESIDENT AND CHIEF EXECUTIVE OFFICER AL NOVAK CANDIDLY ANSWERS SOME TOP-OF-MIND QUESTIONS.

AL NOVAK
President and Chief Executive Officer

NOVOSTE FINISHED 2003 WITH DECLINING SALES, WHICH THE COMPANY HAS ATTRIBUTED TO THE INTRODUCTION IN THE SECOND QUARTER OF DRUG-ELUTING STENTS. WILL YOU ELABORATE?

At Novoste, our market opportunity is to re-open previously stented arteries that have occluded (in-stent restenosis), with our Beta-Cath™ System. Naturally, the fewer stent failures, the more we are challenged to maintain our revenues.

In April 2003, Cordis Corporation, a Johnson & Johnson company, received U.S. Food and Drug Administration approval to introduce the first drug-eluting stent in the United States. Clinical trials with these devices have demonstrated a reduction in the rate of in-stent restenosis from the mid-teens to around six percent. Bare metal stents – already on the market – had also been reducing in-stent restenosis, but drug-eluting stents (DES) have shown a more dramatic success rate for patients.

In addition, physicians have begun utilizing DES to treat the failure of bare metal stents with a "stent sandwich." While the "sandwich" is not an approved indication for drug-eluting stents, it is significantly more convenient than arranging and performing vascular brachytherapy procedures such as ours.

While our physician customers value our procedure, they recognize that drug-eluting stents will reduce in-stent restenosis for their patients, and given the convenience of that product versus our own we anticipate that, as a result of DES, the number of vascular brachytherapy procedures will decline during 2004 and then level out. This is despite the economic advantage of using vascular brachytherapy over drug-eluting stents and despite the absence of FDA approval for DES for in-stent restenosis.

WHILE NOVOSTE WAITS TO SEE WHAT THE LONG-TERM IMPACT OF DRUG-ELUTING STENTS HAS ON THE MARKET, WHAT ARE YOU DOING TO MAINTAIN YOUR COMPANY'S VIABILITY?

Planning for the future is not a precise process, but we believe we have the experience necessary to effect and manage a turnaround. Simply, we must do three things: assure that Novoste's cash is properly managed, leverage our assets and look for other meaningful opportunities. In the past, we have done an outstanding job raising capital, and the current management team is focused on preserving and adding to the Company's cash reserves. In fact, we are very proud to have managed the Company in such a way as to increase cash by nearly $6 million in 2003 – a trying time in which our Company faced increased competition from Guidant and the introduction of drug-eluting stents. Yet we are a disciplined team. And we will make whatever operational decisions that are necessary to minimize the use of cash and yet assure that we have future opportunities.

Our single most important asset is our people and Novoste has a terrific group of employees. Early on, they recognized vascular brachytherapy (VBT) treatment as an extraordinary opportunity for the Company and our customers, and they have made VBT enormously successful. As a result, vascular brachytherapy was the standard of care for in-stent restenosis and Novoste was, by far, the industry leader prior to the introduction of drug-eluting stents. We know that investors examine management and employees' effectiveness, as well as products, when they make their investment decisions. Consequently, we must take careful steps to assure that our Company's organizational structure fits our revenue opportunity. Our team understands that challenge – of constraining costs while determining the Company's future.

Needless to say, we are pleased with all of our employees. However, we are particularly proud of our field sales people. They have been extremely loyal and effective in challenging times. Our direct sales force – both in the United States and Europe – is among the most clinically knowledgeable groups of people working in medical sales today. For instance, our sales people in 2003 generated nearly $61 million in revenue, amid the DES introduction and a highly challenging year. Therefore, we know that leveraging our sales force is our most significant short-term opportunity. Management is focused on obtaining distribution opportunities that will allow our salespeople to be clinically relevant and utilize their chief skill, which is demonstrating the clinical usefulness of new technology in challenging cardiology cases.

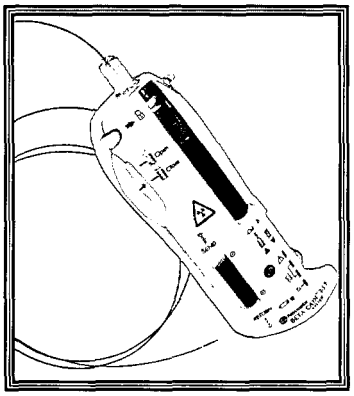
Finally, to mitigate the risk presented by DES to vascular brachytherapy, and to add value to the Company, we bid on several acquisition opportunities in 2003 which we were unsuccessful in obtaining. The Company will continue to aggressively explore acquisition opportunities and will pursue those that it determines to be in the best interest of the Company and its shareholders.

WHAT MOTIVATED NOVOSTE TO PURCHASE GUIDANT CORPORATION'S VASCULAR BRACHYTHERAPY BUSINESS?

Until early 2004, Novoste and Guidant shared – about 50/50 – the vascular brachytherapy (VBT) market. Our Beta-Cath™ System has a longer half-life than Guidant's Galileo® system: 29 years versus 28 days. Having a longer half-life allowed our system to remain in the field for six months before servicing, compared to a monthly service

requirement on Guidant's system. Recently, we obtained FDA approval to extend this service interval to one year. For that reason, we believe that Novoste's solution costs less, and it is easier to use and maintain by the cardiologist, oncologist and physicist.

On April 22, we announced that Novoste entered into an agreement whereby we acquired certain assets of Guidant. As a consequence of this, Guidant will exit the VBT business. We can now consolidate VBT into one organization – Novoste – that has the greatest stake in VBT's success and the only one with approved technology to treat in-stent restenosis. The agreement with Guidant makes sense economically for us and for Guidant's VBT customers as well.



BETA-CATH™

Although we do not expect to double our market share in this transaction, we are confident it will improve Novoste's economic position. Furthermore, this transaction will assure those Guidant customers who want to or must use VBT that a dedicated company exists to provide a product that will meet and exceed their expectations.

YOUR CASH POSITION IS STRONG, AS THE COMPANY GENERATED $6 MILLION IN CASH IN 2003. WHAT ARE YOUR PLANS REGARDING ACQUISITIONS?

As indicated before, we always have sought to acquire businesses – and their products – which make sense for our sales force to distribute. Along with disciplined cost control, we believe the first step is sensible distribution agreements, which help assure that our cash flows are not supporting losses. We are not shy about considering transactions that could require additional financing, provided they offer additional revenue and cash flow that will ensure our turnaround.

WHY DID YOU SUSPEND THE MOBILE AND BRAVO II TRIALS?

Throughout 2003, management continually assessed the Company's position – financially and organizationally. During those evaluations, we made some tough restructuring decisions, including the suspension in August 2003 of the MOBILE trial and in March 2004 of the BRAVO II trial. While both trials attempted to demonstrate the utility of vascular brachytherapy for the treatment of peripheral vascular disease in different sites in the body – MOBILE for legs and BRAVO II for dialysis grafts – they were suspended only after considerable scrutiny. For example, the enrollment rate in the MOBILE trial was such that we would likely not see commercial approval of a product for at least three years. Regarding the BRAVO II trial, we learned that while VBT reduced interventions, it did not extend the life of the arterial-venous graft.

While the reasons for suspending the trials were slightly different, we determined that for the short and long term it would be most appropriate to realign our priorities and deploy our resources to other areas, ensuring the Company's repositioning in the cardiology market.

WHERE MIGHT NOVOSTE'S BEST OPPORTUNITIES OCCUR?
Obviously, it would be great if we could find a market opportunity that leverages both our vascular brachytherapy technology and our direct sales capability. At this point, one possibility is using radiation to treat Atrial Fibrillation or A-fib, the leading cause of stroke in the United States. It is estimated that 2.5 million people have A-fib, with about 250,000 being diagnosed each year in the United States. It is believed that electrical activity emanating in the pulmonary veins is responsible for a significant portion of A-fib episodes among these patients.

We believe that Beta radiation – because of its very short drop-off of radiation of between four to six millimeters – may be an appropriate energy source to create a lesion that may isolate the aberrant electrical activity. Many companies, including Novoste, are aggressively pursuing this opportunity. Our solution may be easy to deliver to the site, but has some drawback in that the result is not known for about seven to ten days, which is the time necessary for cell death to occur after Beta radiation is applied. However, we know episodes of A-fib have declined substantially as a result of the application of some energy source to the pulmonary vein region, and the profile of Beta radiation leads us to believe that we may have an appropriate solution. It will take several years to prove those results in the United States since the follow-up period, which is required to ascertain whether A-fib episodes actually have diminished, is at least 12 months. Nevertheless, it is appropriate, in the absence of other solutions, that we pursue this area unless we find either that another solution holds more promise or that our technology is found not to work.

We also have considered opportunities that would diversify our product offerings, strengthening our position in the cardiology market. Without identifying specific companies or opportunities, we have focused on areas that provide the best use of our sales force's skills – helping to solve complex cases in the cardiac cath lab. Other areas may be those that are not of significant interest to the larger companies competing in the stent arena. We may consider distributing products such as total occlusion devices, closure devices and embolic protection devices. Those are areas where we think we can make a difference – because our sales skills are focused on clinical utility.

WHAT WILL IT TAKE TO GET THERE?
Quite frankly, Novoste's management is focused on bringing other opportunities into the Company. We must remain disciplined in the use of our cash. Therefore, it is not appropriate to complete deals that cannot deliver real results. We will measure those results against how successful we are in optimizing our present VBT business and inaugurating new revenue streams, which must contribute to profitability. We believe we can do those things.

We look forward to the challenge of not only completing our turnaround, but also becoming a vital Company which can make a contribution to our physician customers, their patients, our employees and our shareholders.

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2003.

☐ **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 or any amendment to this Form 10-K ☐.

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

As of March 1, 2004, there were 16,331,068 shares of Common Stock outstanding. The aggregate market value of voting stock held by non-affiliates of the Registrant was approximately $58,275,683 based upon the closing sales price of the Common Stock on June 30, 2003 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 30, 2003 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 2004 Annual Meeting of Stockholders, which the Registrant intends to file not later than 120 days following December 31, 2003, are incorporated by reference to Part III of this Form 10-K Report.

NOVOSTE CORPORATION
FORM 10-K
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PART IV

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 transluminal 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 some of the patients who receive bare metal 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 F 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 primarily been generated from the marketing of the Beta-Cath™ System, but beginning in 2003, we started to sell and distribute stents on a limited basis in Europe, pursuant to a distribution agreement with Orbus Medical Technologies, Inc. (See Note 15 in Notes to Consolidated Financial Statements included in this Form 10-K). During 2003, 92% of our 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 16, included in this Form 10-K.

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 Percutaneous Transluminal Coronary Angioplasty (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 $30,000 to $50,000 per procedure; and the average recuperation period following discharge from the hospital is at least four to six weeks. In 2003, approximately 390,000 CABG procedures were performed in the United States. Several new minimally invasive surgical techniques, which have been commercialized, 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 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. After 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 2003, 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 $10,000 to $15,000, or less than one-half of the average cost of CABG. The length of stay and recuperation period is 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 after 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 initiates 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 that 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 1,600,000 PTCA procedures performed in 2003.

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 15% to 20% of the patients who receive bare metal 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 that 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 stents are continually being developed to make the occurrences of restenosis less frequent. The

newest innovation is a drug eluting stent (DES). This is a product (as discussed further in "Competition; Rapid Technological Change") that utilizes a standard stent platform but with a polymer coating and a therapeutic drug attached to the polymer. The drug eludes off the polymer over time and into the vessel, reducing the incidence of restenosis by over half as compared to a bare metal stent (BMS). Johnson & Johnson received FDA approval for its Cypher DES in April of 2003 and, by the end of the year, captured approximately 60% of the U.S. stent market. In March 2004 Boston Scientific Corporation received FDA approval for its DES product, Taxus, with Medtronic and Guidant both pursuing projects to bring DES to the market. We believe that stainless steel stents or BMS will continue to be used because of their well received past performance and lower product costs. However, we also believe that DES will be the mainstay for interventional cardiologists because of their success against restenosis in both trials and clinical practice. The restenosis rates in the DES trials range around 7% versus an average of 15% with BMS. While this technology impacts our market opportunity negatively, Novoste believes that the overall number of stent procedures will grow significantly. We believe smaller restenosis rates multiplied by a larger base is likely to keep VBT both commercially viable and clinically relevant as the back-up technology to this new breed of stents. Regardless of which stent platform is utilized, there is a restenosis rate associated with each type, and it is that rate of restenosis that will determine how often VBT will be used. Additionally, we believe that in many labs, the cost of using DES is deemed to be excessively high compared to the incremental gain in restenosis. For example, drug eluting stent's average selling price is approximately $3,000 whereas that of BMS is approximately $900. These labs use DES but only in defined areas where BMS restenosis rates are believed to be higher. We believe that VBT will continue to be used as a clinical tool, as well as an integral piece of a cost benefit program built around utilizing BMS. Nevertheless, since the introduction of drug-eluting stents in April 2003, we have seen a wider acceptance of that product in the medical community and a decline in sales of our VBT products. We expect that sales of our VBT products will continue to decline, resulting in a future reduction of our revenues.

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 being 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. The radiation isotopes are reusable 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 cardiology distribution network, by leveraging our brachytherapy assets and know-how where feasible by our ability to execute product development and clinical trials; and by being disciplined in our financial management. 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 continued to respond to customer demand in 2003 by introducing product enhancements and innovations to enable interventional cardiologists greater

ability to treat in-stent restenosis. During 2003, we introduced several product improvements designed to enhance the performance of the Beta-Cath™ System and to reduce the proximity of the radiation oncologist to the sterile field in which the procedure is undertaken. In the future, we plan to provide a longer service interval for our transfer device, which will simplify the maintenance and handling of that portion of the system, which stores the radiation and permits the source train to be sent to the treatment area and returned for storage.

- Expanding into those markets where we believe there is a potential for growth and where that growth will provide a reasonable business opportunity. We plan to execute those clinical trials that will allow us to test the use of our vascular brachytherapy technology know-how and assets. While there is no guarantee that these trials will provide a result that will lead to commercialization of a product, we will use prudence in assessing the business opportunity available to us prior to commencing a trial and we will monitor the trials performance on an ongoing basis to assure commercialization assumptions remain on track. Where assumptions have changed or the clinical trial is not meeting our expectations, we will take appropriate action to assure appropriate use of our resources. For instance in 2003 we gained approval from the FDA to modify the BRAVO Trial to include the patients that better reflect the core of the renal failure population in need and to terminate the MOBILE Trial whose enrollment was not paced for timely completion.
- We also plan to seek growth through the distribution of products manufactured by others in addition to those we manufacture ourselves. We will enter into distribution agreements that will allow us to continue to assist our cardiology customers in the treatment of complex coronary diseases.
- Improving our financial performance by applying our resources to products that can generate near term revenue and profits. We plan to exercise discipline over financial matters and strive to operate in a fashion that will minimize the use of our cash balances while we seek opportunities for growth. 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 balance and operating profitably will allow us to fund our operating and product development activities internally.

Our goals and strategies are aimed at creating a company that is recognized for innovative, clinically superior and economically beneficial therapeutic solutions for the treatment of vascular disease. Our vision is to be recognized as a 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 30mm, 40mm and 60mm lengths, with the longer length intended for use on longer lesions.

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. Two versions of the catheter were sold in the United States in 2003: 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. We plan to phase out sales of the 5.0F System in 2004.

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 lesions.
- *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 during the labeled service life interval (six months) as disclosed on the calibration certificate. 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. 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.

Research and development expenses, which include the cost of clinical trials, for the years ended December 31, 2003, 2002, and 2001 were approximately $11,986,000, $13,300,000 and $12,756,000, respectively. We conducted numerous clinical trials to provide the basis for approval by the FDA of several versions of the Beta-Cath™ System.

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.

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 is able to treat areas unable to be addressed with the current 5.0F 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.

New Products and Applications

Our development efforts have focused 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 (**B**eta **R**adiation for treatment of **A**rterial-**V**enous graft **O**utflow) 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.

In 2001, we gained approval from the FDA to modify the BRAVO Trial to include the patients that better reflect the core of the renal failure population. Specifically, the trial was modified to include patients with thrombosed grafts. Additionally, the trial endpoints were changed from primary patency at 6 months to primary

patency at 3 months. The shorter follow-up is associated with the decreased time to failure for thrombosed patients. The BRAVO trial protocol included 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 had anticipated completion of the enrollment of the 215 patients in the second half of 2003. As of December 31, 2003, enrollment in the modified BRAVO Trial had reached 80 patients. This enrollment reflects a slower than projected enrollment rate with an associated delay in approval.

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 was expected to include 410 patients from 30 sites in North America and Europe. Patients were to be assigned at random for either standard percutaneous catheter-based revascularization therapy followed by vascular brachytherapy or standard therapy alone.

In December 2003 we requested and gained approval from the FDA to terminate the MOBILE Trial. This decision was reached based on the slow enrollment, the length of time required to gain approval to commercialize the product, and the preliminary results of the patient treatments.

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 includes 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 67 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 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 result in a lengthy sales process. In addition to our multidiscipline sales force calling on these customers, we have a team of professionals who help the hospitals through this licensing process with both the United States Nuclear Regulatory Commission ("NRC") and appropriate state regulatory agencies. 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 being analyzed or 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 2003.

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 all suppliers of components must 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 und Unweltdiagnostik GmbH (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, 2003, 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 have been established extending through 2007.

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 to manufacture the transfer devices at its Norcross location was received in February 2004. 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 or 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 Europe 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 patents 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.

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

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

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

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 other 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. Litigation or interference proceedings 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 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.

In 2003, Johnson and Johnson ("J&J") discontinued its vascular brachytherapy product, the CHECKMATE SYSTEM™, and exited the market. Guidant continues to offer vascular brachytherapy products that compete directly with the Novoste Beta-Cath™ System and has substantially greater capital resources and experience at introducing new products than does Novoste. 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 2003 the Beta-Cath™ System maintained approximately 50% of the vascular brachytherapy market worldwide.

A number of companies are researching additional ways to incorporate coatings and drugs into stent platforms as they pursue new innovation in stents. Along with new stent designs, these drug coatings represent revolutionary advancements in the performance of stents as defined by the rate of restenosis. J&J released its DES in April of 2003 and captured over 60% of the U.S. stent market with this single product alone. Boston Scientific Corporation received FDA approval to launch its version in March 2004. Medtronic and Guidant are expected to follow over the next two years pending FDA approval. We believe there are also studies being pursued by both J&J and Boston Scientific to use DES for the treatment of in-stent restenosis. With the rate of restenosis declining and new competitive technologies potentially reducing the in-stent restenosis market in which Novoste operates, we could face challenges in maintaining our revenues through sales of our VBT products.

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, post market 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 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 record keeping requirements including complaint 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 (MDR) 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 the 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 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. 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 which we believe provides us with the greatest opportunity to generate revenue growth, we restructured our European operations in the fourth quarter of 2001 and consolidated our 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 health care 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 $11,000,000. 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 effect on our business, financial condition or results of operations.

EMPLOYEES AND CONSULTANTS

During 2003, we engaged in a restructuring of our management organization and significantly reduced our work force in three separate reductions. In January, 37 employees were terminated, which included 2 members of senior management. In June and July, a reorganization of the field sales force was undertaken by the termination of 2 Area Directors and 13 Area Clinical Trainers. Further restructuring occurred in August with the termination of 39 corporate employees, including 1 member of senior management. As a result, during the year, nearly 30% of our work force worldwide, or 91 employees, were terminated by the restructuring.

As of December 31, 2003 we directly employed 198 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 are 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 2003 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.

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

As discussed previously, several companies have developed additional ways to incorporate coatings and drugs into stent platforms as they pursue new innovations in stents. Along with new stent designs, these drug coatings represent revolutionary advancements in the performance of stents as defined by the rate of restenosis. Johnson & Johnson released its DES product in April of 2003 and captured over 60% of the stent market with this single product. Boston Scientific Corporation will launch its DES version in March 2004. Medtronic and Guidant are expected to follow over the next two years pending FDA approval. We believe there are also studies being pursued by both Johnson & Johnson and Boston Scientific Corporation to use DES for the treatment of in-stent restenosis. With the rate of restenosis declining and new competitive technologies potentially reducing the in-stent restenosis market in which Novoste operates, we could face challenges in maintaining our revenues through sales of vascular brachytherapy products.

In addition, Guidant continues to compete directly with Novoste for market acceptance of vascular brachytherapy and has substantially greater resources and experience at introducing new products than does Novoste. We may not be able to compete effectively against Guidant in the vascular brachytherapy market if they develop products, which are more effective than our products and are preferred by the cardiologists in treating in-stent restenosis. Also, because of our sole dependence on the Beta-Cath™ System, our operating results could be negatively affected if Guidant competed against us solely by reducing the price of its products.

Since the introduction of drug-eluting stents in April 2003, we have seen a wider acceptance of that product in the medical community and a decline in sales of our VBT products. We expect that sales of our VBT products will continue to decline, due to the market acceptance of drug-eluting stents and competitive pressures from other vascular brachytherapy products, resulting in a future reduction of our revenues.

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.

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 patent 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 patent 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.

Defending against intellectual property claims could be expensive and disruptive to our business.

We cannot assure you that others will not obtain and assert patents or other intellectual property rights against us affecting essential elements of our business. From time to time, in the ordinary course of our business, we have been subject to legal proceedings and claims relating to the intellectual property rights of others, and we expect that third parties will continue to assert intellectual property claims against us, particularly as we expand into those markets where we believe there is a potential for growth. We diligently defend our intellectual property rights, but intellectual property litigation is expensive and time consuming, and successful infringement claims against us could result in significant monetary liability or prevent us from operating our business, or portions of our business. In addition, resolution of claims may require us to obtain licenses to use intellectual property rights belonging to third parties or possibly to cease using those rights altogether. Any of these events could have an adverse effect on our business, financial condition and operating results.

Compliance With Applicable Government Regulations Will Be Expensive And Difficult.

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

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

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

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

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

In order for us to market the Beta-Cath™ System in certain 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 maintain market acceptance, the rate and size of expenditures incurred in our operations, product development and business expansion, 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. In February 2004, the Company served notice to terminate the lease of the headquarters building in Norcross, Georgia in anticipation of a move to more efficient space.

ITEM 3. LEGAL PROCEEDINGS

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

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

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

On October 6, 2003, the Company filed a law suit in the United States District Court for the District of Connecticut against Scott Sacane, Durus Capital Management, LLC, and Durus Life Sciences Master Fund, Ltd., which suit sought recovery of profits made by the defendants from purchases and sales of Novoste's common stock that represented short-swing transactions under Section 16(b) of the Securities Exchange Act of 1934. The Company learned, on August 23, 2003, through filings made by Scott Sacane and Durus Capital Management, LLC with the United States Securities and Exchange Commission that Durus Life Sciences Master Fund, LLC became a greater than 10% shareholder of Novoste in October 2002. Subsequent to that time, Durus Life Sciences Master Fund, Ltd., under the direction of Mr. Sacane and Durus Capital Management, LLC, purchased and sold, and sold and purchased, shares of Novoste common stock during periods of less than six months, in violation of the insider trading laws.

The Company is diligently pursuing this lawsuit and believes that the lawsuit is the best course of action to protect the interests of Novoste and its shareholders. At the present stage of the litigation it is not possible to predict the outcome of the case or any potential recovery for the Company.

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	56	President and Chief Executive Officer
Donald J. Webber	41	Chief Operating Officer
Andrew Green	35	Vice President, Regulatory and Clinical Affairs
Daniel G. Hall	57	Vice President, Secretary and General Counsel
Adam G. Lowe	41	Vice President, Quality Assurance
Subhash C. Sarda	54	Acting Chief Financial Officer, Vice President, Finance, and Controller
Susan D. Smith	54	Vice President, Human Resources
Robert N. Wood, Jr	50	Vice President, Sales and Marketing

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.

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, 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.

Subhash C. Sarda. Mr. Sarda joined Novoste Corporation in November 2002 as Corporate Controller, and has served as Acting Chief Financial Officer since August 2003. In February 2004, he was promoted to the

position of Vice President, Finance and continues to be responsible for duties of Controller and Acting Chief Financial Officer. Prior to joining Novoste Corporation, Mr. Sarda worked in a number of multi-national companies with responsibilities for operational and SEC reporting. Mr. Sarda, a CMA, ACA, holds an MBA from Temple University, Philadelphia, and a B.A. in Accounting from studies pursued at the London School of Accountancy, London, UK.

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 1, 2004 was 88 excluding beneficial owners of shares that 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 in each of the last eight quarters is as follows:

Quarter Ended	High	Low
Year Ended December 31, 2002		
March 31, 2002	$11.27	$6.55
June 30, 2002	$ 8.75	$4.62
September 30, 2002	$ 5.05	$3.35
December 31, 2002	$ 7.22	$3.97
Year Ended December 31, 2003		
March 31, 2003	$ 9.08	$6.83
June 30, 2003	$ 9.02	$6.01
September 30, 2003	$ 5.62	$4.03
December 31, 2003	$ 5.39	$4.30

On March 1, 2004, the last reported sale price for the Common Stock was $4.85.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected financial data shown below for the fiscal years ended December 31, 2003, 2002 and 2001, and as of December 31, 2003 and 2002, 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, 2000 and 1999, and as of December 31, 2001, 2000 and 1999, have been derived from our 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,				
	2003	2002	2001	2000	1999
	(In thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Net sales	$ 62,901	$ 69,030	$ 69,908	$ 6,530	$ 1,823
Costs and expenses:					
Cost of sales	24,315	27,313	19,164	4,258	1,642
Impairment charge	—	6,900	—	—	—
Research and development	11,986	13,300	12,756	17,119	22,889
Sales and marketing	19,485	26,875	34,654	15,651	6,606
General and administrative	8,237	8,335	9,324	6,321	3,775
Restructuring and other expenses	—	—	1,214	—	—
Loss from operations	(1,122)	(13,693)	(7,204)	(36,819)	(33,089)
Other income	254	642	2,095	3,746	2,169
Net loss	$ (868)	$ (13,051)	$ (5,109)	$ (33,073)	$(30,920)
Basic and diluted net loss per share (1)	$ (0.05)	$ (0.80)	$ (0.32)	$ (2.13)	$ (2.30)
Weighted average shares outstanding (1)	16,313	16,268	16,152	15,517	13,433
Consolidated Balance Sheet Data:					
Working capital	$ 39,364	$ 30,496	$ 40,482	$ 53,742	$ 38,821
Total assets	61,407	67,520	82,911	77,073	49,367
Long-term liabilities	—	5	203	401	—
Accumulated deficit	(135,302)	(134,434)	(121,384)	(116,275)	(83,201)
Total shareholders' equity	53,244	52,765	64,728	67,042	43,065

(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. We 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, we received U.S. marketing approval for the 30-millimeter Beta-Cath™ System from the FDA and subsequently shipped the first commercial system on November 27, 2000. The number of commercial sites in the U.S. is now approximately 400. In 2003, Novoste entered into license agreements for marketing bare metal stents in Europe as an adjunct to the VBT business.

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, due to the costs of launching the Beta-Cath™ System in the U.S. Beginning in 2001, losses began to decline as revenue increased and development costs and clinical trials began to decrease. However, we have not been able to maintain consistent profitability as we have experienced competitive pressures from other VBT products and alternative products such as drug-eluting stents. In particular, since the introduction of drug-eluting stents in April 2003, we have seen a wider acceptance of that product in the medical community and a decline in sales of our VBT products. We expect that sales of our VBT products will continue to decline in 2004, resulting in a future reduction in our revenues.

Fiscal year 2003 was a challenging year as we relaunched a redesigned 3.5F diameter catheter system in January, saw the introduction of drug-eluting stents in April, and saw the curtailment of the MOBILE trial in July; all of which adversely affected our financial performance. As a result, we had a net loss for the year ended December 31, 2003 of $868,000, or $0.05 per share. At December 31, 2003, we had an accumulated deficit of approximately $135,302,000.

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 such differences 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 stents 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 regular 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. At December 31, 2002, a revenue reserve of $2,150,000 was recorded in connection with the relaunch of the 3.5F catheters recalled during the third quarter of 2002. This reserve covered the anticipated exchange of 5.0F catheters for 3.5F catheters by customers during the first quarter of 2003. As these exchanges occurred, the reserve was released and the revenue recognized. No new reserve has been recorded because the Company's exchange policy has expired.

Radiation and Transfer Devices and Amortization of Costs

The Company retains ownership of the radiation source trains (RSTs) that are manufactured by third party vendors and transfer devices (TDs), which historically have been purchased from vendors, but are expected to be manufactured by the Company in the future. 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 of 12 months and 36 months for RSTs and TDs, respectively, 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 requiring matching RSTs. The acquisition of these various length RSTs are based upon demand forecasts derived from available information provided by the Company's sales and marketing department. 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 3.5F 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 $6,900,000 were warranted (See Note 13). Management will continue to evaluate its long-lived assets in accordance with SFAS No. 144. As of December 31, 2003 the net book value of 5.0F assets was zero.

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 $442,000 and $1,135,000 for the years ending December 31, 2003 and 2002, respectively. Bad debts were recovered in 2003 through aggressive collection efforts for older accounts and tighter collection policies. This recovery was $377,000 for 2003, in contrast to a bad debt expense of $372,000 for 2002 and $590,000 for 2001.

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 $1,242,000 at December 31, 2003 and $844,000 at December 31, 2002. The increase was due primarily to establishing a reserve for parts related to the 5.0F systems and for parts related to the early-design 3.5F systems that were made obsolete by product enhancements.

RESULTS OF OPERATIONS

Comparison of Years Ended December 31, 2003 and 2002

The net loss for the year ended December 31, 2003 was $868,000, or $0.05 per share, as compared to a net loss of $13,051,000, or $0.80 per share, for the year earlier.

Net Sales and Revenues. Net sales and revenues were $62,901,000 for the year ended December 31, 2003 as compared to $69,030,000 for the year ended December 31, 2002. Revenues recorded in the United States for

the year ended December 31, 2003 were $57,915,000 as compared to $64,746,000 for the year ended December 31, 2002. Comparatively, international revenue increased 16.4% to $4,986,000 in 2003 compared to $4,284,000 in 2002. The revenue decline is due to lower sales for catheters of 12% and lower lease revenue for radiation devices of 73%. The decline in catheters was the result of lower utilization of VBT in treating coronary patients. This lower utilization was attributed by the Company to the introduction of drug-eluting stents into the U.S. market in April 2003. We expect that sales of our VBT products will continue to decline in 2004, resulting in a future reduction in our revenues. The decline in lease revenue was attributed to competitive pressure to renew leases at considerably lower costs to the customer.

Both the U.S. and international markets were affected by the conditions described above. The international market, however, was helped by the sale of stents, a new product licensed for sale beginning in January 2003, which contributed $620,000, or 13%, to our international revenues.

Cost of Sales. Cost of sales for the year ended December 31, 2003 was $24,315,000 or 38.7% of net sales as compared to cost of sales of $34,213,000 (including $6,900,000 of impairment and related charges) or 49.6% of net sales for the year ended December 31, 2002. Cost of sales for 2003 returned to a level more in line with historical results as compared to 2002. Cost of sales for 2002 was unusually high due to the $6,900,000 impairment charge, or 10% of sales. Excluding the impairment charge, cost as a percent of sales declined due to lower manufacturing and service costs resulting from reengineering our production function, absence of the cost of replacement catheters associated with the recall of the 3.5F catheters during third quarter of 2002, and lower amortization cost of radiation devices, as the older units become fully depreciated. As such, 2003 gross margin on an absolute basis was lower than 2002 (excluding the impairment charge of $6,900,000) due to lower revenues, but higher on a percentage basis as a result of the actions taken above.

Research and Development Expenses. Research and development expenses decreased 9.9% to $11,986,000 for the year ended December 31, 2003 from $13,300,000 for the year ended December 31, 2002. The decline was attributed to reduced costs associated with the MOBILE trial, which was discontinued in July 2003; to lower engineering and operating costs which were elevated in 2002 due to the product recall in August 2002 and which entailed product redesign and FDA filings; and to completion of reengineering our production function.

Sales and Marketing Expenses. Sales and marketing expenses decreased 27.5% to $19,485,000 for the year ended December 31, 2003 as compared to $26,875,000 for the previous year. Costs have declined mainly due to lower revenues and the variable costs associated with revenue, such as commissions, travel, marketing incentives and trade show participation. Other factors include fewer trade show activities than in 2002, when the 3.5F catheter system was introduced, and the closing of the sales office in Brussels in March 2002.

General and Administrative Expenses. General and administrative expenses decreased 1.2% to $8,237,000 for the year ended December 31, 2003 from $8,335,000 for the year ended December 31, 2002. The decline was attributed to the completion of a computer systems upgrade project and to on going cost reduction efforts in 2003.

Other Income. Net other income decreased 60.4% to $254,000 for the year ended December 31, 2003 from $642,000 for the prior year. The decrease in other income is primarily attributable to the decrease in interest income as a result of the low interest rate environment in 2003.

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 was 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 5.0F assets. Cost of sales included 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.

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 as a result of a shift to cash-equivalent investments from short-term investments, combined with low interest rates.

Liquidity and Capital Resources

During the year ended December 31, 2003, Novoste cash and cash equivalents increased to $33,177,000 from $21,928,000 at the end of 2002.

For the year ended December 31, 2003, cash generated from operations was $9,192,000, compared to $10,709,000 in 2002. Both years benefited from non-cash charges of depreciation and amortization of assets and radiation devices acquired in earlier years. Cash from operations was lower in 2003 compared to 2002 because of contraction of the Company's business volume. In 2003, $4,072,000 in funds from reduction of receivables, inventories and prepaids were offset by $4,280,000 reduction in payables and accruals. In 2002, cash from operations benefited from the collection of receivables which were high at the beginning of the year following the first full year of Novoste's commercial sales and the ramp up of customers and, correspondingly, receivables. In 2002, cash from receivables collection exceeded reduction in payables and accruals by $6,243,000. The recognition of revenue (See Note 1 to the Consolidated Financial Statements included in this Form 10-K)

deferred due to the 3.5F product recall accounted for $2,150,000 of the $2,258,000 reduction in unearned revenue. We expect the aggregate changes in the working capital components of receivables, inventories, payables and expense accruals to remain stable and cash from operations will be driven by earnings and the non-cash charges of depreciation and amortization.

Net cash provided by investing activities for the year ended December 31, 2003, was $1,142,000. $5,422,000 in cash was provided by shorter maturities of available-for-sale securities, $723,000 was used for purchase of property and equipment, but at a lower level than in 2002 due to completion of manufacturing facilities in September 2002 and $3,557,000 was used for the purchase of additional radiation and transfer devices, but at a lower level than 2002, as the number of new customer sites has stabilized and only replacement equipment was purchased.

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, 2003 provided $476,000 in net cash as compared to using $250,000 for the year ended December 31, 2002 and providing $1,654,000 for the year ended December 31, 2001.

In 2003, Novoste received $768,000 from the exercise of stock options and sales of our common stock to employees under the stock purchase program, purchased $109,000 of treasury stock under the stock repurchase program and repaid $183,000 for capital leases of computer equipment.

The Company's principal source of liquidity at December 31, 2003 consisted of cash, cash equivalents and short-term investments of $39,402,000 as compared to $33,575,000 as of December 31, 2002.

The Company has a $10 million revolving line of credit with a financial institution (lender) that was previously due in February 2004 but has been renegotiated to mature in May 2004. At December 31, 2003, 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, 4.25% plus 1%. The Company has 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, 2003, the Company was in compliance with all covenants of the loan agreement. However, at December 31, 2002, the Company was in violation of the tangible net worth covenant of the loan agreement and the lender 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 was 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 not to exceed $500,000, subject to further limitations. Each letter of credit will have an expiration 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 agreed 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, 2003.

The Company believes that existing cash and cash expected to be generated from operations will be sufficient to meet its working capital, financing and capital expenditure requirements through at least 2004. The Company's future liquidity and capital requirements will depend upon numerous factors, including, among others: market demand for its products, especially with the introduction of drug-eluting stents by the Company's competitors and the expected decline in the Company's revenues; 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 offerings or other sources of capital. Additional financing, if required, may not be available on satisfactory terms, or at all.

Commitments

At December 31, 2003 the Company had commitments to purchase $4,683,000 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 2002 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 pricing guidelines have been established extending to 2007.

On June 20, 2001, the Company entered into a manufacturing and supply agreement with Bebig Isotopentechnik und Umweltdiagnostik 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 in 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. The Company exceeded the annual guaranteed payment for 2003.

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 $585,000, $668,000, and $633,000 in 2003, 2002 and 2001, respectively, and have been expensed in cost of sales. Approximately $3,015,000 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 $1,192,000, $1,378,000, and $1,444,000 in 2003, 2002 and 2001, respectively, and have been expensed in cost of sales.

As of December 31, 2003, we had contractual obligations as follows (in thousands):

	Payments due by period				
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Contractual Obligations					
Operating Leases	$ 1,086	$ 670	$ 416	$ —	$ —
Purchase Obligations	11,656	4,683	6,973	—	—
Total	$12,742	$5,353	$7,389	$ —	$ —

Approximately $9,196,000 of our purchase obligations listed above relate to purchase contracts denominated in Euros. This amount was derived from converting such purchase obligations by using a December 31, 2003 conversion rate of $1.25 USD to 1 Euro. As noted above, some of these purchase obligations extend to 2007 and the actual settlement amount may be different from the amount presented based on the conversion rate as of December 31, 2003.

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 January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51* (FIN 46), which addresses the consolidation of entities whose equity holders have either (a) not provided sufficient equity at risk to allow the entity to finance its own activities or (b) do not possess certain characteristics of a controlling financial interest. FIN 46 sets forth a model to evaluate potential consolidation of these entities, known as variable interest entities (VIEs), based on an assessment of which party to the VIE, if any, absorbs a majority of the exposure to its expected losses, receives a majority of its expected residual returns, or both (the "primary beneficiary"). FIN 46 also requires disclosures about VIEs that a company is not required to consolidate but in which it has a significant variable interest. FIN 46 is effective for all new VIEs created or acquired after January 31, 2003. For VIEs created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after March 15, 2004 except for companies with special purpose entities which must apply the provisions of FIN 46 to those special purpose entities no later than the first reporting period ending after December 15, 2003. FIN 46 has not had any material impact on our results of operations, financial condition or cash flows as of December 31, 2003.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities*. The standard became effective for us, generally, for contracts entered into or modified after June 30, 2003. The adoption of SFAS 149 has not had any material impact on our results of operations or financial position as of December 31, 2003.

In May 2003, the Financial Accounting Standards Board (FASB) issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS 150 improves the accounting for certain financial instruments that under the previous guidance, issuers could account for as equity. SFAS 150 requires that those instruments be classified as liabilities in statements of financial position. This statement is effective for financial instruments entered into or modified after May 31, 2003. On October 29, 2003, FASB deferred for an indefinite period the application of the guidance in SFAS 150. FASB decided to defer the application of SFAS 150 until it could consider some of the resulting implementation issues associated with the measurement and recognition issues. SFAS 150 does not have a material impact on our results of operation or financial position.

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, 2003, the Company had $33,177,000 in cash and cash equivalents with a weighted average interest rate of .74% and $6,225,000 in available-for-sale investments with a weighted average interest rate of 1.31%. At December 31, 2002, the Company had $21,928,000 in cash and cash equivalents with a weighted average interest rate of .91% and $11,647,000 in available-for-sale investments with a weighted average interest rate of 2.02%.

Foreign Currency Risk

International revenues from the Company's foreign direct sales and distributor sales comprised 7.9%, 6.2% and 7.5% of total revenues for the years ended December 31, 2003, 2002 and 2001, 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, 2003.

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. During 2003, the Euro increased against the dollar to 1.25 from 1.04, a 20% increase. This resulted in a $530,000 translation adjustment, which is included with Other Comprehensive Income.

Approximately $9,196,000 of our purchase obligations listed under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" relate to purchase contracts denominated in Euro. This amount was derived from converting such purchase obligations by using a December 31, 2003 conversion rate of $1.25 USD to 1 Euro. As noted above, some of these purchase obligations extend to end of 2007 and the actual settlement amount may be different from the amount presented based on the conversion rate as of December 31, 2003.

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.

ITEM 9A. CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures.* As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934). Based on this evaluation, our Chief Executive Officer and Acting Chief Financial Officer have concluded that our disclosure controls and procedures are effective in timely notification to them of information we are required to disclose in our periodic 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) *Changes in Internal Control.* During the fourth quarter of fiscal year 2003, there have been no significant changes in our internal control over financial reporting that have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information on directors required by Items 401, 405 and 406 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, 2003.

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, 2003, 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, 2003.

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, 2003.

ITEM 14. PRINCIPAL ACCOUNTING FEES & SERVICES

The information required by Item 9(e) of Schedule 14A is incorporated herein by reference to the Company's Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2003.

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*

The following schedule is filed herewith:

All other schedules for which provision is made in the applicable accounting regulations of the SEC are not required under the related instructions or are inapplicable and, therefore, have been omitted.

3. *Exhibits.*

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

(b) We filed the following report on Form 8-K during the fiscal quarter ended December 31, 2003:

On October 22, 2003, we filed current report on Form 8-K to disclose that we issued a press release announcing Novoste's earnings for the quarter ended September 30, 2003. A copy of the release was furnished as an exhibit under Item 9 of such Form 8-K.

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 March 11, 2004.

NOVOSTE CORPORATION

By /s/ ALFRED J. NOVAK

Alfred J. Novak
Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

We the undersigned officers and directors of Novoste Corporation, hereby severally constitute and appoint Alfred J. Novak and Subhash C. Sarda, and each of them singly, our true and lawful attorneys, with full power to both of them and each of them singly, to sign for us and in our names in the capacities indicated below, any amendments to this Report on Form 10-K and generally to do all things in our names and on our behalf in such capacities to enable Novoste Corporation to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all the requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant, in the capacities indicated on March 11, 2004.

Signatures	Titles
/s/ ALFRED J. NOVAK **Alfred J. Novak**	Chief Executive Officer (Principal Executive Officer)
/s/ SUBHASH C. SARDA **Subhash C. Sarda**	Acting Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ J. STEPHEN HOLMES **J. Stephen Holmes**	Director
/s/ CHARLES E. LARSEN **Charles E. Larsen**	Director
/s/ JUDY LINDSTROM **Judy Lindstrom**	Director
/s/ STEPHEN I. SHAPIRO **Stephen I. Shapiro**	Director
/s/ THOMAS D. WELDON **Thomas D. Weldon**	Director
/s/ WILLIAM E. WHITMER **William E. Whitmer**	Director

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, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in the index at Item 15. These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

Ernst & Young LLP

Atlanta, Georgia
February 6, 2004

NOVOSTE CORPORATION

CONSOLIDATED BALANCE SHEETS
(in thousands, except number of shares data)

	December 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,177	$ 21,928
Short-term investments	6,225	11,647
Accounts receivable, net of allowance of $442 and $1,135, respectively	5,206	6,758
Inventory, net	2,439	3,927
Prepaid expenses and other current assets	480	986
Total current assets	47,527	45,246
Property and equipment, net	6,997	9,542
Radiation and transfer devices, net	6,304	11,353
Receivable from officers	—	283
Other assets	579	1,096
Total assets	$ 61,407	$ 67,520
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,492	$ 2,176
Accrued expenses	6,483	9,967
Unearned revenue	188	2,429
Capital lease obligations	—	178
Total current liabilities	8,163	14,750
Long-term liabilities		
Capital lease obligations	—	5
Total liabilities	8,163	14,755
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; 16,371,997 and 16,351,953 shares issued, respectively	164	164
Additional paid-in capital	187,880	187,813
Accumulated other comprehensive income	733	190
Accumulated deficit	(135,302)	(134,434)
Treasury stock, at cost, 42,929 and 118,077 shares, respectively	(172)	(445)
Unearned compensation	(59)	(523)
Total shareholders' equity	53,244	52,765
Total liabilities and shareholders' equity	$ 61,407	$ 67,520

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per-share data)

	Year Ended December 31,		
	2003	2002	2001
Net sales	$62,901	$ 69,030	$69,908
Cost of sales	24,315	27,313	19,164
Impairment charge	—	6,900	—
Gross margin	38,586	34,817	50,744
Operating expenses:			
Research and development	11,986	13,300	12,756
Sales and marketing	19,485	26,875	34,654
General and administrative	8,237	8,335	9,324
Restructuring and other expense	—	—	1,214
Total operating expenses	39,708	48,510	57,948
Loss from operations	(1,122)	(13,693)	(7,204)
Interest income	317	747	2,164
Interest expense	(32)	(105)	(75)
Other income (expense)	(31)	—	6
Total other income	254	642	2,095
Net loss	$ (868)	$(13,051)	$ (5,109)
Net loss per share—basic and diluted	$ (0.05)	$ (0.80)	$ (0.32)
Weighted average shares outstanding—basic and diluted	16,313	16,268	16,152

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock		Unearned Compensation	Total
	Shares	Amount				Shares	Amount		
Balance at January 1, 2001	16,095	$161	$184,512	$ (94)	$(116,274)	(6)	$(24)	$(1,238)	$67,043
Exercise of stock options at $3.20 to $27.00	117	1	1,258	—	—	—	—	—	1,259
Deferred compensation relating to issuance of stock options to officers	—	—	839	—	—	—	—	(595)	244
Issuance of stock under Employee Stock Purchase Plan, 36,776 shares at $14.93 and 12,482 shares at $7.15	49	1	638	—	—	—	—	—	639
Issuance of restricted stock to an officer (3,000 shares) and consultant (1,000 shares) at $23.02	4	—	92	—	—	—	—	(92)	—
Amortization of unearned compensation	—	—	—	—	—	—	—	948	948
Other equity transactions	—	—	18	—	—	—	—	—	18
Comprehensive loss:									
Foreign currency translation adjustment	—	—	—	(314)	—	—	—	—	(314)
Net loss	—	—	—	—	(5,109)	—	—	—	(5,109)
Total comprehensive loss	—	—	—	—	—	—	—	—	(5,423)
Balance at December 31, 2001	16,265	$163	$187,357	$(408)	$(121,383)	(6)	$(24)	$ (977)	$64,728

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)

	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 $1.00 to $6.65	61	$ 1	$ 336	$—	$ —	26	$ 111	$ —	$ 448
Deferred compensation relating to issuance of stock options	—	—	365	—	—	—	—	(365)	—
Issuance of stock under Employee Stock Purchase Plan, 25,497 shares at $4.08 and 21,353 shares at $3.927	26	—	104	—	—	21	84	—	188
Amortization of unearned compensation	—	—	—	—	—	—	—	273	273
Stock repurchase	—	—	—	—	—	(159)	(616)	—	(616)
Compensation expense relating to accelerated vesting of stock options to former officer	—	—	197	—	—	—	—	—	197
Cancellation of unvested equity awards issued to officers	—	—	(546)	—	—	—	—	546	—
Comprehensive loss:									
Unrealized loss	—	—	—	(19)	—	—	—	—	(19)
Foreign currency translation adjustment	—	—	—	617	—	—	—	—	617
Net loss	—	—	—	—	(13,051)	—	—	—	(13,051)
Total comprehensive loss	—	—	—	—	—	—	—	—	(12,453)
Balance at December 31, 2002	16,352	$164	$187,813	$190	$(134,434)	(118)	$(445)	$(523)	$52,765

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)

	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 $6.65	4	$ —	$ 292	$ —	$ —	101	$ 382	$—	$ 674
Issuance of stock under Employee Stock Purchase Plan, 18,519 shares at $5.0582	18	—	94	—	—	—	—	—	94
Amortization of unearned compensation	—	—	—	—	—	—	—	138	138
Stock repurchase	—	—	—	—	—	(26)	(109)	—	(109)
Revaluation of variable stock awards	—	—	(283)	—	—	—	—	271	(12)
Compensation expense relating to fair market value of stock options to non employees	—	—	49	—	—	—	—	(19)	30
Cancellation of unvested restricted stock awards	(2)	—	(85)	—	—	—	—	74	(11)
Comprehensive loss:									
Unrealized loss	—	—	—	13	—	—	—	—	13
Foreign currency translation adjustment	—	—	—	530	—	—	—	—	530
Net loss	—	—	—	—	(868)	—	—	—	(868)
Total comprehensive loss	—	—	—	—	—	—	—	—	(325)
Balance at December 31, 2003	16,372	$ 164	$187,880	$ 733	$(135,302)	(43)	$(172)	$ (59)	$53,244

See accompanying notes.

NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2003	2002	2001
Cash flows from operating activities:			
Net loss	$ (868)	$(13,051)	$ (5,109)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization of property and equipment	3,295	3,125	2,413
Stock based compensation expense	145	470	1,192
Depreciation of radiation and transfer devices	8,606	9,241	5,088
Impairment charge	—	5,065	—
Provision for doubtful accounts	(410)	288	591
Changes in assets and liabilities:			
Accounts receivable	2,043	9,326	(12,410)
Inventory	1,521	(85)	(2,586)
Prepaid expenses and other current assets	508	36	(541)
Other assets	890	(285)	(465)
Accounts payable	(753)	(2,033)	644
Accrued expenses	(3,527)	(1,001)	5,536
Unearned revenue	(2,258)	(387)	2,216
Net cash provided by (used in) operating activities	9,192	10,709	(3,431)
Cash flows from investing activities:			
Maturity/sale of short-term investments	16,686	35,573	49,690
Purchase of short-term investments	(11,264)	(15,536)	(50,718)
Purchase of property and equipment, net	(723)	(2,730)	(4,921)
Purchase of radiation and transfer devices	(3,557)	(12,124)	(13,141)
Net cash provided by (used in) investing activities	1,142	5,183	(19,090)
Cash flows from financing activities:			
Proceeds from issuance of common stock	768	636	1,916
Purchase of treasury stock	(109)	(616)	—
Repayment of capital lease obligations	(183)	(270)	(262)
Net cash provided by (used in) financing activities	476	(250)	1,654
Effect of exchange rate changes on cash	439	408	233
Net increase (decrease) in cash and cash equivalents	11,249	16,050	(20,634)
Cash and equivalents at beginning of period	21,928	5,878	26,512
Cash and cash equivalents at end of period	$ 33,177	$ 21,928	$ 5,878
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 15	$ 106	$ 74
Non cash investing and financing activities:			
Assets acquired under capital leases	$ —	$ —	$ 105

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 developing clinically superior and economically beneficial therapeutic solutions for the prevention and treatment of vascular disease. A major activity is 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 and other coronary applications.

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. In 2003, the Company expanded its offering to the coronary market by licensing stents for sale outside the U.S.

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 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. At December 2002, net sales were adjusted by approximately $2,150,000 for 3.5F catheters that were sold to customers but subsequently exchanged after the recall when the new, redesigned 3.5F diameter catheters were relaunched in January 2003.

In the opinion of management, all adjustments considered necessary for a fair presentation of Novoste's financial results and condition have been recorded. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States.

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 stents 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.

Sales for stents and catheters are final and revenue is recorded at time of shipment. Product is not returnable except for shipping errors or warranty claims. In addition, in 2002, the Company recorded a reserve of $2,150,000 for anticipated exchanges related to the 3.5F product, which was recorded as a reduction to net sales and was included in unearned revenue. This revenue was recognized during 2003 as these exchanges occurred.

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 regular 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 2003, 2002 and 2001, approximately $1,239,000, $4,547,000 and $6,814,000, respectively, of net sales related to the lease of radiation transfer devices were recorded.

Accounts Receivable

Accounts receivable at December 31, 2003 and 2002 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 2003 or 2002. The Company performs periodic credit evaluations of its customer's financial condition and generally does not require collateral. Allowances for uncollectible accounts receivable represent estimates of expected credit losses and returns of product sold based on periodic reviews of customer accounts and historical collection experience. The balance of $377,000 added to income during 2003 represents recovery of accounts previously reserved, in contrast to an expense of $372,000 for 2002 and $590,000 for 2001.

Receivable From Officers

In October 2001, the Company adopted a split-dollar life insurance plan for all officers. The Company matched officer contributions to the plan and also provided an advance for related payroll taxes. The payroll tax

advance was reflected as a receivable from officers on the balance sheet. The advances were unsecured and were 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 left the Company for any reason, retired or in any way terminated or withdrew from the plan, the life insurance company was obligated to repay the Company for the tax advances prior to settlement of the account with the officer. The Company has ceased accepting further contributions to the plan from Executive Officers. All officers have withdrawn from the plan and all receivables have been returned to the Company. At December 31, 2003 and 2002, the receivable from officers' balance was $0 and $282,000, respectively.

Advertising Costs

All advertising costs are expensed as incurred. Approximately $547,000, $838,000, and $1,350,000 were charged to advertising expense for the years ended December 31, 2003, 2002 and 2001, 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 3,094,000, 3,590,000 and 3,506,000 related primarily to stock options are not included in the per share calculations for 2003, 2002 and 2001, 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. 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 Statements of Shareholders' Equity. 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 7.9%, 6.2% and 7.5% of total revenues for the years ended December 31, 2003, 2002 and 2001, respectively. The Company experienced an immaterial amount of transaction gains and losses in 2003, 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 2003, 2002 and 2001 are reflected in Other Comprehensive Income (Loss) on the Consolidated Statements of Shareholders' Equity. During 2003, the Euro appreciated against the dollar approximately 20%, resulting in approximately $530,000 of Other Comprehensive Income.

Inventories

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

Property and Equipment

Property and equipment, including amounts under capital leases, 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 or economic life, if shorter. Repairs and maintenance are expensed as incurred.

Long-lived Assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), long-lived assets are reviewed for impairment whenever events indicate that their carrying amount may not be recoverable. In such reviews, estimated undiscounted future cash flows associated with these assets are compared with their carrying value to determine if a write-down to fair value is required (Note 13).

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 2003, 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, 2003, unearned revenue under leases approximated $162,000, compared to $279,000 at December 31, 2002.

During 2000, the first year of commercial sales, the Company estimated the useful life of the 5.0F diameter system to be eighteen months, based on the information available at that time. During early 2002, the Company concluded that, based on new testing and experience, the components of the radiation device should be accounted for separately and determined the estimated useful lives of RSTs was 12 months and transfer devices was 36 months. Accordingly, depreciation has been recorded over the new estimated lives, starting at the beginning of the first quarter 2002.

In February 2002, the Company received FDA approval of the smaller diameter 3.5F system and began commercial sales at that time. Although engineering improvements could be expected to improve the expected life of the components of the new system, the Company has continued to use the same estimated useful lives as the older 5.0F system, pending the analysis of data supporting a different life.

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 $5,065,000 and an accrual of $1,835,000 for related contractual commitments were recognized in the second quarter for the estimated fair value of the 5.0F diameter system (Note 13). 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 extended through December 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 13).

The impact of the change in estimate of useful lives in 2002 was as follows (in thousands, except per share data).

Change	Increase (Decrease) Cost of sales 2002
Change in radiation devices life from 18 months to 12 months (RST's) and 36 months (TD's)	$(3,838)
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 13)	6,865
Acceleration of useful lives of 60mm 5.0F RST's and TD's	612
Net impact	$ 3,639
Net effect on loss per share	$ (0.22)

The impact on cost of sales for 2003 is immaterial.

At December 31, 2003, equipment with a cost of approximately $25,554,000, before accumulated depreciation and reserves of approximately $19,250,000, was subject to operating leases (See Note 5).

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. Costs paid for patents are capitalized and amortized over the life of the patent.

Shipping Costs

All shipping costs incurred by the Company are classified as cost of sales.

Stock Based Compensation

SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) sets forth accounting and reporting standards for stock-based employee compensation plans (Note 12). 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* (APB 25) and related interpretations. Under APB 25, no compensation expense is recognized for stock option grants to employees for which the terms are fixed. The Company grants stock options generally for a fixed number of shares to employees, directors, consultants and independent contractors with an exercise price equal to the fair market value of the shares at the date of grant. Compensation expense is recognized for increases in the estimated fair value of common stock for any stock options with variable terms.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.*

In December 2002, the Financial Accounting Standards Board (FASB) issued SFAS 148, *Accounting for Stock-Based Compensation—Transition and Disclosure* (SFAS 148). SFAS 148 amends SFAS 123 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 2003, 2002 and 2001: 10-year treasury bill interest rates of 4.22%, 4.24% and 4.22%, respectively; no dividend yields; volatility factor of the expected market price of the Company's common stock of 0.80, 1.24 and 1.29, in 2003, 2002 and 2001, respectively; and a weighted-average expected life of the option of five years for 2003, 2002 and 2001.

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 (in thousands, except per share amounts):

	Year Ended December 31,		
	2003	2002	2001
Net Loss, as reported	$ (868)	$(13,051)	$ (5,109)
Add: Total stock-based employee compensation expense included in net loss	145	470	948
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(3,914)	(7,006)	(13,497)
Pro forma net loss	$(4,637)	$(19,587)	$(17,658)
Earnings per share:			
Basic and diluted-as reported	$ (0.05)	$ (0.80)	$ (0.32)
Basic and diluted-pro forma	$ (0.28)	$ (1.20)	$ (1.09)

Recent Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51* (FIN 46), which addresses the consolidation of entities whose equity holders have either (a) not provided sufficient equity at risk to allow the entity to finance its own activities or (b) do not possess certain characteristics of a controlling financial interest. FIN 46 sets forth a model to evaluate potential consolidation of these entities, known as variable interest entities (VIEs), based on an assessment of which party to the VIE, if any, absorbs a majority of the exposure to its expected losses, receives a majority of its expected residual returns, or both (the "primary beneficiary"). FIN 46 also requires disclosures about VIEs that a company

is not required to consolidate but in which it has a significant variable interest. FIN 46 is effective for all new VIEs created or acquired after January 31, 2003. For VIEs created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after March 15, 2004 except for companies with special purpose entities which must apply the provisions of FIN 46 to those special purpose entities no later than the first reporting period ending after December 15, 2003. FIN 46 has not had any material impact on our results of operations, financial condition or cash flows as of December 31, 2003.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities* (SFAS 149). SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*. The standard became effective for us, generally, for contracts entered into or modified after June 30, 2003. The adoption of SFAS 149 has not had any material impact on our results of operations or financial position or cash flows as of December 31, 2003.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS 150 improves the accounting for certain financial instruments that under the previous guidance, issuers could account for as equity. SFAS 150 requires that those instruments be classified as liabilities in statements of financial position. This statement is effective for financial instruments entered into or modified after May 31, 2003. On October 29, 2003, FASB deferred for an indefinite period the application of the guidance in SFAS 150. FASB decided to defer the application of SFAS 150 until it could consider some of the resulting implementation issues associated with the measurement and recognition issues. The Company has not determined the resulting impact of the adoption of this statement on its results of operations, financial positions, or cash flows.

Reclassifications

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

2. SHORT-TERM INVESTMENTS

At December 31, 2003 and 2002, 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.

Available-for-Sale Investments

Available-for-sale investments at December 31, 2003 were as follows (in thousands):

	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Loss	Estimated Fair Value
Money market	$ 15,459	$ —	$ —	$15,459
Commercial paper	4,896	—	—	4,896
Asset backed bonds	1,609	—	(7)	1,602
Corporate bonds	2,608	—	(1)	2,607
Government bonds	4,018	2	—	4,020
Total available-for-sale investments	28,590	$ 2	$ (8)	$28,584
Less amounts classified as cash equivalents	(22,359)			
Unrecognized net loss	(6)			
	$ 6,225			

Available-for-sale investments at December 31, 2002 were as follows (in thousands):

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

The amortized cost and estimated fair value of available-for-sale investments in debt securities and other investments at December 31, 2003, by contractual maturity, were as follows (in thousands):

	Adjusted Cost	Estimated Fair Value
Due in less than 1 year	$26,981	$26,982
Due in 1-2 years	1,097	1,096
Due in 3-5 years	512	506

3 INVENTORIES

Inventories are comprised of the following (in thousands):

	December 31, 2003	December 31, 2002
Raw materials	$1,511	$2,878
Work in process	124	202
Finished goods	804	847
Inventory, net	$2,439	$3,927

Inventory reserves increased from $844,000 at December 31, 2002 to $1,242,000 at December 31, 2003. The increase is due to establishing a reserve for parts related to the 5.0F systems and for parts related to the early design 3.5F systems that were made obsolete by product enhancements.

4. PROPERTY AND EQUIPMENT

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

	December 31, 2003	December 31, 2002
Furniture and fixtures	$ 1,211	$ 1,413
Office equipment	4,142	5,293
Laboratory equipment	991	1,008
Leasehold improvements	2,208	2,213
Production equipment	8,205	8,472
	16,757	18,399
Less: Accumulated Depreciation and Amortization	(9,760)	(8,857)
Property and equipment, net	$ 6,997	$ 9,542

5. RADIATION AND TRANSFER DEVICES

Radiation and transfer devices are stated at cost and are comprised of the following (in thousands):

	December 31, 2003	December 31, 2002
Radiation and transfer devices, gross	$ 25,554	$ 25,003
Less: Accumulated depreciation	(19,250)	(13,650)
Radiation and transfer devices, net	$ 6,304	$ 11,353

During 2002, an impairment charge of $5,065,000 was recognized in the second quarter for 5.0F radiation devices (See Note 13).

6. ACCRUED EXPENSES

Accrued expenses are comprised of the following (in thousands):

	December 31, 2003	December 31, 2002
Salaries, wages and benefits	$2,353	$3,819
Radiation and disposals	1,598	2,154
Clinical trials	783	434
Operating expenses and royalties	643	1,381
Professional fees	584	634
Due to customers	310	1,173
Sales and use taxes	212	372
	$6,483	$9,967

7. 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 borrowed $4 million against the line of credit and repaid the loan by the end of the year. At December 31, 2003 and 2002, 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 receivable. Interest on outstanding balances is payable on the first of each month, calculated on the outstanding balance, and accrues at a rate of the bank's prime rate, 4.25% at December 31, plus 1%. The Company granted a first priority security interest in substantially all assets of the Company to the lender. By agreement between the Company and the lender, the maturity date of the original loan agreement between the parties had been extended to February 27, 2003, and by further agreement, the maturity date has been extended to May 27, 2004.

The Company also has letters of credit available under the revolving line of credit. The lender will issue 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.

8. 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, 2003, lease payments under capital leases were $183,000. Amortization of assets for capital leases was $150,000 and $262,000 for 2003 and 2002, respectively. Such amounts are recorded as depreciation expense and included in operating expenses. During 2003, all obligations under capital leases were satisfied and no future lease obligations exist at December 31, 2003.

9. 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 tax assets for federal and state income taxes are as follows (in thousands):

	December 31, 2003	December 31, 2002
Deferred tax assets:		
Net operating loss carryforwards	$ 51,433	$ 50,684
R&D tax credit carryforwards	2,920	2,432
Provision for doubtful accounts	57	57
Other	3	3
Accruals/reserves	3,034	4,154
Property and equipment	1,142	396
	58,589	57,726
Valuation allowance for deferred tax assets	(58,589)	(57,726)
Net deferred tax assets	$ —	$ —

At December 31, 2003 and 2002, 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 their benefit. No income taxes were paid during 2003, 2002, or 2001. As of December 31, 2003, the Company has approximately $108,038,000 of net operating losses (NOL) for U.S. federal income tax purposes. Such losses expire in 2007 through 2023. Of the NOL carry forwards, approximately $13,617,000 represent cumulative exercises of non-qualified stock options which 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. As of December 31, 2003, the Company has approximately $13,695,000 of foreign net operating losses related to its European subsidiaries. Additionally, the Company has approximately $2,920,000 in research and development (R&D) tax credits that expire in 2008 through 2023 unless utilized earlier. The NOL and R&D tax credits are available to offset future income taxes payable, if any. The Tax Reform Act of 1986 contains provisions that limit carry forwards and R&D tax credits available for use in any given year in the event of significant changes in ownership interests, as defined.

A reconciliation of the provision for income taxes to the federal statutory rate is presented below for the years ended December 31 as follows (in thousands):

	2003	2002	2001
Tax benefit at statutory rate	$(295)	$(4,437)	$(1,737)
State tax, net of federal benefit	(23)	(482)	(204)
R&D tax credit	(571)	(925)	(441)
Other	101	346	577
Valuation allowance for deferred income tax	788	5,498	1,805
	$ —	$ —	$ —

10. 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 Grants

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 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. Under the 2001 Plan, 429,855 shares were granted, 94,748 shares were exercised and 403,415 shares were canceled in 2003, and 118,335 shares remain available for grant as of December 31, 2003.

Effective February 12, 2002, the Company's Board of Directors adopted the Novoste Corporation 2002 Broad-Based Stock Plan (the "2002 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 2002 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 2002 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 2002 Plan, 96,050 shares were granted, 5,000 shares were exercised, and 82,600 shares were cancelled in 2003, and 23,150 shares remain available for grant as of December 31, 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, 2000	2,452,441	$1.00–$49.25	$22.69
Options granted	1,425,350	6.65– 34.75	9.52
Options exercised	(117,188)	3.20– 27.00	10.75
Options forfeited	(260,045)	6.65– 49.25	25.11
Outstanding at December 31, 2001	3,500,558	1.00– 49.25	17.53
Options granted	1,413,274	3.70– 8.10	4.86
Options exercised	(87,525)	1.00– 6.65	5.12
Options forfeited	(1,240,266)	3.70– 49.25	22.54
Outstanding at December 31, 2002	3,586,041	3.20– 49.25	11.14
Options granted	526,405	4.50– 8.39	5.67
Options exercised	(104,748)	3.20– 7.46	6.44
Options forfeited	(914,134)	3.70– 49.25	13.58
Outstanding at December 31, 2003	3,093,564	3.20– 49.25	9.59
Exercisable at December 31, 2003	1,673,809	3.20– 49.25	12.29

At December 31, 2003 the Company has 3,235,049 shares of common stock reserved for issuances under these employee and director stock option arrangements and 128,364 shares of common stock reserved for issue under the Employee Stock Purchase Plan (Note 12).

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	1,214,390	8.98	$ 4.28	314,150	$ 4.17
5.01– 7.00	876,877	8.09	6.53	602,892	6.58
7.01– 10.50	201,125	8.84	7.92	60,050	7.73
10.51– 13.38	178,285	5.12	11.62	178,285	11.62
13.39– 21.94	151,375	5.86	15.24	111,911	15.22
21.95– 22.50	167,062	6.80	22.50	126,088	22.50
22.51– 24.69	118,800	4.36	24.00	116,900	24.00
24.70– 49.25	185,650	4.85	33.17	163,533	33.08
	3,093,564	7.80	9.59	1,673,809	12.29

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 $1,793,000, which will be expensed over the four-year vesting period of these options: $0, $127,000 and $415,000 were expensed in 2003, 2002 and 2001, respectively. Approximately 37,500 of these options awarded to a former officer of the Company were forfeited during 2000, reducing the incurred compensation by $73,000 to $1,720,000.

In April 2001, options to purchase 101,000 shares were granted at $14.71 per share. These grants were subject to shareholder approval in June 2001. When approval was obtained, the market price per share exceeded the exercise price, and the Company incurred compensation of $839,000, which will be expensed over the vesting period of these options. The vesting period allowed for one-quarter vesting of the options on the date of grant and the remainder to be vested one-quarter over the next three grant date anniversaries. Approximately $114,000, $210,000 and $345,000 were expensed in 2003, 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 $197,000 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 options for 19,375 shares to an officer of the Company as a replacement award to previously canceled options. The Company recorded $91,000 in compensation expense associated with the issuance of these awards. In 2003, the Company granted 11,500 shares of stock options to non-employees, which had a total fair market value of $49,000 at their grant date. Under SFAS 123, the fair market value of these grants are to be amortized over their vesting period ranging from five months to four years. The Company recorded $30,000 in compensation expense associated with the issuance of these grants.

The weighted-average fair value of options granted during 2003 is $3.50.

Since inception the Company granted a total of 56,450 shares of restricted Common Stock authorized under the various plans 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. In 2003, 2,475 shares were canceled due to termination of employment. As of December 31, 2003, 46,288 of these restricted shares have vested. The remaining 188 shares will vest through October 2004. 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 $25,000, $55,000 and $434,000 in 2003, 2002 and 2001, respectively. The value of the remaining shares awarded totaled $3,000 at December 31, 2003 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.

Stock Buy-Back Program

In August 2002, the Company announced a stock buy-back program, which authorized the purchase of up to $5 million of common stock in the open market. Under the program, no shares will knowingly be purchased from

officers or directors of the Company. Depending on market conditions and other factors, these purchases may be commenced or suspended at any time or from time-to-time without notice. Shortly after the announcement, the Company suspended the program when the voluntary product recall of 3.5F catheters was initiated. In August 2003, the Company announced the extension of the stock buy-back program originally authorized last year for an additional one year period and increased the authorized expenditure for stock repurchase up to $7 million. As of December 31, 2003, 185,400 shares have been purchased for $725,000.

11. COMMITMENTS AND CONCENTRATIONS OF SUPPLIERS

The Company is committed under operating leases for its facility and various equipment. Rent expense was approximately $783,000, $677,000 and $956,000 for 2003, 2002 and 2001, respectively. The total future minimum rental payments are as follows (in thousands):

2004	$ 670
2005	376
2006	40
	$1,086

In February 2004, the Company served notice to terminate the lease of its corporate office location in anticipation of a move to more efficient space. As of the notification date, the net book value of leasehold improvements was $3,000.

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, $585,000, $668,000 and $632,000 in 2003, 2002 and 2001 and have been expensed in cost of sales. Approximately $3,015,000 remains to be paid as of December 31, 2003.

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 $1,192,000, $1,378,000 and $1,444,000 in 2003, 2002 and 2001, respectively, and have been expensed in cost of sales.

The Company has long-term contracts with the suppliers of Radiation Source Trains, a key component of the Beta-Cath-system. These contracts expire between 2005 and 2007. Commitments under the contracts were $10,446,000 and $13,646,000 at December 31, 2003 and 2002, respectively. Approximately $1,000,000 of these commitments relate to purchase of 5.0F radiation source trains and $250,000 relates to radiation disposal and have 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.

At December 31, 2003 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, and accrued $154,000 for decommissioning the source train manufacturing facility, which is included in assets and accrued liabilities and is being amortized over the life of the facility. In addition, the Company has accrued $221,000 for isotope seed disposal at December 31, 2003, which is recorded in accrued expenses. The disposal 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, 2003, the Company, except for the following, is not aware of any such claims and assertions that are material to the Company's financial statements.

In June 2003, Calmedica LLC (Calmedica) filed suit against the Company alleging infringement of patents owned by Calmedica. Novoste has been aware of the patents owned by Calmedica and believes our products do not infringe on the patents. While the Company and its counsel believe that Calmedica is not likely to be successful on the merits, defense of the case could require the expenditure of significant time and resources. Due to the high degree of uncertainty associated with this matter, no accruals have been recorded.

12. 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 2003, 2002 and 2001 the Company matched 33⅓% of the first 6% of employee contributions, aggregating $199,000, $293,000 and $239,000, 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, 2003, 121,136 shares have been purchased under the Plan.

13. RESTRUCTURING CHARGES, IMPAIRMENT CHARGES, AND OTHER EXPENSE

Restructuring charges of $1,214,000 were recorded in 2001 primarily related to a reduction in workforce in Europe and 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 of $654,000 in 2002.

During 2001, the Company contributed $440,000 for an 8% ownership interest in an equity method investment. This amount was included with research and development expense in the accompanying Statements of Operations as a result of the impairment of that investment.

Impairment and related charges of $6,900,000 associated with the Company's U.S. operations, 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 be used 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, with a carrying amount of $8,593,000, were impaired and wrote them down by $5,065,000 to their estimated fair value of $3,528,000 and accrued $1,835,000 for related contract commitments, resulting in impairment and other related charges of $6,900,000 for the second quarter of 2002. Fair value was based on expected future net cash flows to be generated by the transfer devices and radiation source trains during their remaining service lives, discounted at the risk-free rate of interest. The remaining fair value is amortized ratably over the estimated useful life of these assets, which extended through December 31, 2003. At December 31, 2003 the net book value of 5.0F impaired assets was zero.

Eighty-seven employees located in the U.S. were terminated during the year ended December 31, 2003, to align the Company's staffing with current market conditions. Termination costs were recorded and paid in 2003. These costs are included in operating expense on the consolidated statement of operations for the year ended December 31, 2003.

14. 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 2003, 2002 and 2001, approximately $30,000, $0 and $20,000, respectively, was charged to operations as amortization of deferred compensation under these agreements in accordance with their vesting terms.

15. RELATED PARTY TRANSACTIONS

On December 23, 2002, the Company signed a Distribution Agreement with Orbus Medical Technologies, Inc., (Orbus) a manufacturer of cardiology products. The Company's Chief Executive Officer, Mr. Al Novak is also the Chairman of Orbus. During 2003, the Company purchased $771,000 of product from Orbus. As of December 31, 2003, the Company has prepaid $169,000 for future product purchases and had $341,000 in inventory. In the year ending December 31, 2003, Novoste had net sales of $620,000 from this product line.

16. 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 two geographic areas: United States and Rest of World (Canada, Europe, Australia, Asia and South America).

The Company's net sales, net income (loss), long-lived assets and total assets by geographic area are as follows (in thousands):

Net sales	United States	Rest of World	Consolidated
2003	$57,915	$ 4,986	$ 62,901
2002	64,746	4,284	69,030
2001	64,697	5,211	69,908

Net Income (Loss)	United States	Rest of World	Consolidated
2003	$ (932)	$ 64	$ (868)
2002	(8,109)	(4,942)	(13,051)
2001	2,953	(8,062)	(5,109)

Long-lived assets	United States	Rest of World	Consolidated
2003	$12,110	$ 1,191	$ 13,301
2002	18,304	2,591	20,895

Total assets	United States	Rest of World	Consolidated
2003	$57,264	$ 4,143	$ 61,407
2002	62,616	4,904	67,520

17. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

	(In thousands, except per share amounts)			
Fiscal 2003	First Quarter Ended March 31	Second Quarter Ended June 30	Third Quarter Ended September 30	Fourth Quarter Ended December 31
Net sales and revenue	$20,705	$17,608	$13,531	$11,057
Cost of sales	7,066	6,318	5,535	5,396
Impairment Charge	—	—	—	—
Gross Margin	13,639	11,290	7,996	5,661
Income (loss) from operations	2,029	1,091	(1,554)	(2,688)
Net income (loss)	2,137	1,153	(1,519)	(2,639)
Net income (loss) per share	0.13	0.07	(0.09)	(0.16)

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	$16,824	$14,655	$14,619
Cost of sales	6,678	6,214	6,774	7,647
Impairment Charge	—	6,900	—	—
Gross Margin	16,254	3,710	7,881	6,972
Income (loss) from operations	3,180	(8,592)	(3,381)	(4,900)
Net income (loss)	3,402	(8,551)	(3,287)	(4,615)
Net income (loss) per share	0.21	(0.52)	(0.20)	(0.29)

SCHEDULE II. VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

	(In thousands)			
	Balance Beginning of Period	Charged to Operations	Deduction From Reserve(*)	Balance End of Period
Fiscal Year 2003				
Allowance for Doubtful Accounts	$1,135	$(377)	$(316)	$ 442
Inventory Reserves	844	398	—	1,242
Fiscal Year 2002				
Allowance for Doubtful Accounts	$ 878	$ 372	$(115)	$1,135
Inventory Reserves	15	829	—	844
Fiscal Year 2001				
Allowance for Doubtful Accounts	$ 311	$ 590	$ (23)	$ 878
Inventory Reserves	—	15	—	15

* write offs of uncollectible accounts

Shareholder Information

HEADQUARTERS

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INDEPENDENT AUDITORS

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Atlanta, Georgia

LEGAL COUNSEL

Hogan & Hartson LLP
Washington, D.C.

ANNUAL MEETING

The annual meeting for shareholders will take place on Tuesday, June 15, 2004 beginning at 8:30 a.m. at the Atlanta Marriott Gwinnett Place, 1775 Pleasant Hill Road, Duluth, 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 1, 2004 was 88, 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 10 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, 2003	**$ 9.08**	**$ 6.39**
June 30, 2003	**$ 9.16**	**$ 5.90**
September 30, 2003	**$ 6.15**	**$ 3.93**
December 31, 2003	**$ 5.49**	**$ 4.11**
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

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