NOVOSTE CORP /FL/
Form 10-K
March 16, 2005
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2004.

¨ 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.)**
4350 International 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 x No ¨

Indicate by check mark if disclosures of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

As of March 1, 2005, there were 16,334,705 shares of Common Stock outstanding.

The aggregate market value of voting stock held by non-affiliates of the Registrant was approximately $43,366,843 based upon the closing sales price of the Common Stock on June 30, 2004 on the NASDAQ National Market.

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Cautionary Note Regarding Forward-Looking Statements

The forward-looking statements in this Form 10-K are made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended. Our operating results and financial condition have varied and may in the future vary significantly depending on a number of factors. Statements in this Form 10-K which are not strictly historical statements, including, without limitation, statements regarding management s expectations regarding the staged wind-down of our vascular brachytherapy products business, future strategic transactions, if any, possible liquidation and dissolution and future revenues from the sale of our vascular brachytherapy products, 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 w 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 and its subsidiaries. Beta Cath® and the Novoste® logo are trademarks of the Company.

OVERVIEW

On February 22, 2005, we announced that our board of directors has determined that our vascular brachytherapy products business, which is our only business line, is no longer viable and, as a result, has authorized a staged, wind-down of our business. On that date, we also announced that, pursuant to the first stage of our wind-down plan, we will reduce the U.S. workforce in the first quarter of 2005 by 52 employees, from 81 employees. Additionally, the Company notified all its employees outside of the U.S. (16) that they will be terminated in accordance with their contracts and the relevant country s employment regulations in an effort to further reduce the Company s costs. Our board has determined that this decision is necessary to preserve our cash resources and arises as a result of the continuing decline in revenue for our vascular brachytherapy products.

Because of the rapid acceptance of drug-eluting stents in the medical community and their success in reducing in-stent restenosis since their introduction into the U.S. market in April 2003, our revenues have experienced a substantial and sustained decline. We believe that if we were to continue operating our vascular brachytherapy products business, our sales of such products would continue to substantially decline in 2005 as compared to 2004, resulting in a further significant reduction in our revenues and corporate assets.

As previously disclosed, we have been actively seeking new product opportunities, as well as a merger, business combination or other disposition of our business or assets, due to the continuing challenges facing our vascular brachytherapy business. As part of our ongoing review of potential options, we retained an investment banking and strategic advisor, Asanté Partners LLC, in April 2004, to assist us in our efforts to

identify and implement strategic and financial alternatives. If a suitable transaction on acceptable terms does not become available in the relatively near term, we will need to consider other alternatives, which could include liquidation and dissolution.

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As part of our review of potential strategic alternatives, we have received inquiries from, and have engaged in discussions with, companies potentially interested in a merger or business combination with us. Based on these inquiries and discussions, we cannot assure our shareholders that any such transaction will be successfully concluded. Further, even if such a transaction is successfully concluded, the value of the consideration that would be received by, or the transaction value to, our shareholders in such a merger or business combination could be less than the prices at which our common stock has traded in the recent past.

If we were to liquidate and dissolve, we cannot predict when or if we would be able to make a distribution to our shareholders. However, in the event that one or more cash distributions were made after dissolution, we expect that the amount distributed after dissolution would be significantly lower than prices at which our common stock has traded in the recent past, and there can be no assurance that such amount would equal the prices at which our common stock may trade in the future. Any distributions after dissolution would be reduced by cash expenditures during the staged wind-down of our business, and by the ultimate amounts paid in settlement of our liabilities. Prior to authorizing any distribution to shareholders after dissolution, our board of directors would be required to make adequate provision to satisfy known and unknown claims against us, and our liability for such claims may extend for a substantial period of time in the future. As a result, there can be no assurance that we would have sufficient cash available to make any distributions to shareholders after dissolution. If we were to have sufficient remaining cash to make distributions, a substantial period may elapse after dissolution before we would be able to make any such distribution to shareholders, and such distribution, if any, may be made in more than one installment over an extended period of time.

BACKGROUND

Novoste developed the Beta-Cath System, a hand-held device to deliver beta, a low penetration radiation, to the site of a treated blockage in a coronary artery to inhibit 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, we 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. We 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. As described above, in February 2005 we announced that our board of directors has determined that our vascular brachytherapy products business is no longer viable, and as a result, has authorized a staged wind-down of our business. See Overview.

Novoste Corporation is a Florida corporation. We were incorporated in 1987 and remained dormant until May 22, 1992 (date of inception) at which time we began operations. We have had our principal operations in the United States and sales and distribution in Western Europe, Canada, Asia and South America. Prior to the implementation of the staged wind-down of our business, we marketed our 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. In February 2005, Novoste and Orbus mutually agreed to terminate the distribution agreement.

Available Information. We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (SEC). You may read and copy any document

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we file 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 located at http://www.sec.gov.

Our website is located at http://www.novoste.com. We make available, free of charge through our internet site, our 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 our 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. It 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 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. 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 guide wire 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. The length of stay and recuperation period for PTCA procedures is substantially less than those required for CABG.

Though PTCA grew rapidly as a highly effective, less invasive therapy to treat coronary artery disease, the principal limitation of PTCA was the high rate of restenosis, the renarrowing of a treated artery, which often required 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.

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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 artery wall. 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.

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 us 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 that utilizes a standard stent platform, but with a polymer coating and a therapeutic drug attached to the polymer. The drug elutes 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 2003, captured approximately 60% of the U.S. stent market. In March 2004 Boston Scientific Corporation received FDA approval for its DES product, Taxus. 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 particularly in the U.S. because of its success against restenosis in both trials and clinical practice. We believe that the overall number of DES procedures will continue to grow

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significantly in the future, resulting in a substantial decline in the use of VBT products, and in connection therewith, our board of directors has determined that our VBT business is no longer viable and we have, therefore, announced a staged wind-down of our business.

OUR BUSINESS STRATEGY

As described in Business-Overview, we announced on February 22, 2005 that our board of directors has determined that our vascular brachytherapy products business is no longer viable and, as a result, has authorized a staged wind-down of our business. Our board of directors has determined that this decision is necessary to preserve our cash resources.

As previously disclosed, we have been actively seeking new product opportunities, as well as a merger, business combination or other disposition of our business or assets, because of the continuing challenges facing our vascular brachytherapy products business. As part of our ongoing review of potential options, we retained an investment banking and strategic advisor, Asanté Partners LLC, in April 2004, to assist us in our efforts to identify and implement strategic and financial alternatives. If a suitable transaction resolving our future, on acceptable terms, does not become available in the relatively near term, we will need to consider other alternatives, which could include liquidation and dissolution.

PRODUCT DEVELOPMENT AND CLINICAL TRIALS

In connection with the wind-down of our business operations, we have ceased our ongoing product development and clinical trial activities.

Research and development expenses, which include the cost of clinical trials, for the years ended December 31, 2004, 2003 and 2002 were approximately $4,633,000, $11,986,000 and $13,300,000, respectively. During these years, we continued to collect data for post-approval studies in the United States required by the FDA upon original approval of the Beta-Cath System and the 40mm version of the Beta-Cath System, as well as for European clinical trials that evaluated the 60mm Beta-Cath System and the 40mm Beta-Cath 3.5F System. The data obtained from these European trials were used in regulatory submissions to obtain commercial approval of these configurations of the Beta-Cath System.

In addition to the studies mentioned above, two clinical trials were undertaken to evaluate a vascular brachytherapy system (the Corona System) developed by Novoste s Product Development team to treat peripheral indications: the MOBILE Trial, which evaluated VBT in the treatment of in-stent restenosis in lesions of superficial femoral artery (SFA) and popliteal arteries, and the BRAVO Trial, which studied the use of VBT in improving continuous venous outflow in stenosed hemodialysis grafts. Neither of these trials indicated that the use of VBT would provide a significant patient benefit.

At this time, all post-approval studies that were initiated with the Beta-Cath System are either completed or will be completed, with data reported to FDA, by approximately May 31, 2005. The MOBILE Trial is considered completed at this time, as all trial sites have been closed and the Final Report has been issued to FDA and the sites. The BRAVO Trial is in the process of closure, and it is anticipated that the Final Report will be issued to FDA and to the trial sites by May 31, 2005. Therefore, all of Novoste s clinical trial commitments, in the U.S. and outside the U.S., should be met in the second quarter of 2005.

SALES AND MARKETING

In connection with the wind-down of our VBT products business, we have substantially ceased our sales and marketing activities as part of the staged wind-down of the business.

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MANUFACTURING, SOURCES OF SUPPLY AND SCALE-UP

While we ceased manufacturing catheters as of March 1, 2005, we continue to supply catheters from inventory, and continue to service transfer devices and radiation source trains. Our manufacturing operations were 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/ISO 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 . In the past as part of our manufacturing operations, which we have discontinued, we conducted quality audits of suppliers and required that all suppliers of components be in compliance with our requirements and the FDA s quality system regulations.

Beta Radiation Source Train Suppliers

Beginning in 1996, we 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, we entered into a new manufacturing and supply agreement with Bebig to manufacture and supply the Company with radioactive sealed Strontium-90 seed trains. During each calendar year under the four-year contract, the Company guaranteed minimum annual payments to Bebig in varying amounts. All product purchases are credited against the annual guaranteed payment. In the event that the Company did not purchase product to exceed the annual guaranteed payment, the deficiency was due and payable to Bebig within thirty days after the end of each one-year contract period. The final purchase commitment of $250,000 will be paid in the first quarter of 2005 and is fully accrued as of December 31, 2004. There is an obligation of $250,000 to reimburse Bebig for expenses associated with decommissioning the production line. Payment of this obligation will be completed by June 19, 2005, the expiration of this agreement. This is also fully accrued as of December 31, 2004.

On October 14, 1999 Novoste signed a development and manufacturing supply agreement with AEA Technologies WSA 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 development 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 trains by using the development equipment to produce the smaller diameter radiation source 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 Novoste. Annual minimum purchase commitments and pricing guidelines have been established extending to 2006 (see Item 7, Liquidity and Capital Resources). These estimates are subject to negotiation and settlement with AEA. During 2004, Novoste did not reach the minimum purchase commitment level for product and incurred an expense in cost of sales of $695,000 for this shortfall. At the termination of the agreement, Novoste is obligated for costs associated with decommissioning the production facility and $621,000 has been accrued for this purpose and it is expensed in cost of sales.

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

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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 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.

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

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

We have 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 we believe that our products do not infringe the Calmedica patents. While our counsel and we believe that Calmedica is not likely to be successful on the merits, defense of the cases may require the expenditure of significant time and resources.

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 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.

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 is 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

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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 us.

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.

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, 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.

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

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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 our 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 us to commercially distribute our 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.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire-hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with such laws and regulations now or in the future and such laws or regulations could have a material adverse effect on us.

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 25 countries of the European Union, or EU, and Switzerland. Although the medical devices

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directive is intended to ensure free movement within the EU of medical devices that bear the CE marking, many countries in the EU 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.

On February 22, 2005, we announced the staged wind-down of our VBT products business. At that time, we also announced that we have notified all of our employees outside of the U.S. (16) that they will be terminated in accordance with their contracts and the relevant country s employment regulations. We expect that all of our international operations will be discontinued in the near term in connection with our wind-down.

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 us.

EMPLOYEES AND CONSULTANTS

During 2004, we engaged in a restructuring of our management organization and significantly reduced our work force. As of December 31, 2004 we directly employed 98 full-time individuals.

In February 2005, we announced that we were reducing our remaining United States workforce in the first quarter of 2005 by 52 employees, from 81 employees. Additionally, we announced that we have notified all our employees outside of the U.S. (16) that they will be terminated in accordance with their contracts and the relevant country s employment regulations.

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.

On February 22, 2005, we announced that our board of directors has determined that our vascular brachytherapy products business is no longer viable and, as a result, has authorized a staged wind-down of our business. On such date, we announced that, pursuant to the first stage of our wind-down, we are terminating 68 of our remaining 97 worldwide employees in an effort to further reduce our costs. Our board has determined that this decision is necessary to preserve our cash resources and arises as a result of the continuing decline in revenue for our vascular brachytherapy products. Upon completion of our wind-down, we will no longer have an operating vascular brachytherapy business.

As discussed above under Business Overview, we have engaged Asanté Partners LLC to assist us in the exploration of strategic alternatives. Based on the outcome of this process, we expect to determine in the near

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term how best to proceed to maximize shareholder value. However, we cannot predict whether, or when, a transaction will result from this process. In addition, we may need to seek additional funds to finance potential strategic transactions, but may not be able to obtain such funds on satisfactory terms, if at all. If a suitable transaction resolving our future on acceptable terms does not become available in the relatively near term, we will need to consider other alternatives, which could include liquidation and dissolution.

Difficulties efficiently implementing our staged wind-down of business operations could reduce the amount of our remaining corporate assets.

Our board of directors has authorized the staged wind-down of our vascular brachytherapy products business, which is our only business line. Our board has determined that this decision is necessary to preserve our cash resources. During the wind-down of our business, we will need to negotiate the orderly extinguishment of our obligations to creditors. Effectively implementing the wind-down of our business will depend on our ability to maximize the consideration we receive for our assets, minimize the amount we must expend to settle our debts and other liabilities, minimize our contingent liabilities, minimize our operating expenses during the wind-down process and expedite the wind-down process. In the event that we are unable to efficiently implement the wind-down of our business, our corporate assets may be further depleted.

If we were to liquidate and dissolve, any cash amount distributed to shareholders could be significantly lower than prices at which our common stock has traded in the recent past.

If we were to liquidate and dissolve, we cannot predict when, or if, we would be able to make a distribution to our shareholders. However, in the event that one or more cash distributions were made after dissolution, we expect that the amount distributed could be significantly lower than some prices at which our common stock has traded in the recent past, and there can be no assurance that such amount, if any, would equal the prices at which our common stock could trade in the future.

In the event that we liquidate and dissolve and have assets available to distribute to shareholders, our board will need to make provision for the satisfaction of all of our known and unknown liabilities, which could substantially delay or limit our ability to make any distribution to shareholders.

In the event that we liquidate and dissolve, our board of directors will be required to make adequate provision to satisfy our liabilities, including known and unknown claims against us, prior to authorizing any distributions to shareholders after dissolution. The process of accounting for our liabilities, including those that are presently unknown, may involve difficult valuation decisions, which could adversely impact the board s ability to make any such distribution after dissolution in a timely manner. Substantial time may be required for us to determine the extent of our liabilities to known and unknown third party creditors and claimants. Furthermore, pursuant to the Florida Business Corporations Act, we may be liable for known and unknown claims for a substantial period of time in the future. As a result, there can be no assurance that we would have sufficient cash available to make any distributions to shareholders after dissolution. If we were to have sufficient remaining cash, a substantial period may elapse after dissolution before we would be able to make any such distribution to shareholders, and such distribution, if any, may be made in more than one installment over an extended period of time.

In the event that we make one or more distributions after dissolution, our shareholders could be liable to the extent of distributions received if contingent reserves are insufficient to satisfy our liabilities.

In the event of our liquidation and dissolution, if we fail to create an adequate contingency reserve for payment of our expenses and liabilities, each shareholder receiving a distribution after dissolution could be held liable for the payment to creditors of such shareholder s *pro rata* portion of any shortfall, limited to the amounts previously received by the shareholder in distributions from the Company.

If a court holds at any time that we have failed to make adequate provision for our expenses and liabilities or if the amount ultimately required to be paid in respect of such liabilities exceeds the amount available from the

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contingency reserve, our creditors could seek an injunction against the making of distributions after dissolution on the grounds that the amounts to be distributed are needed to provide for the payment of our expenses and liabilities. Any such action could delay or substantially diminish the amount of any cash distributions to shareholders after dissolution.

We may continue to incur the expense of complying with public company reporting requirements.

We have an obligation to continue to comply with the applicable reporting requirements of the Securities Exchange Act of 1934, as amended, even though compliance with such reporting requirements is economically burdensome. In the event that we liquidate and dissolve, in order to curtail such expenses, after filing our certificate of dissolution upon shareholder approval of a plan of liquidation, we might seek relief from the SEC for a substantial portion of the periodic reporting requirements under that Act.

Product liability suits against us could result in expensive and time-consuming litigation and the payment of substantial damages.

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

We have substantially reduced our workforce as part of our wind-down of operations.

During 2004, we engaged in a restructuring of our management organization and significantly reduced our work force. In February 2005, we announced that we were reducing our remaining United States workforce in the first quarter of 2005 by 52 employees, from 81 employees. Additionally, we have notified all of our employees outside of the U.S. (16) that they will be terminated in accordance with their contracts and the relevant country s employment regulations. As a result, we currently have extremely limited personnel resources, which may make it difficult for us to efficiently implement the staged wind-down of our business.

We are highly dependent on key management personnel.

We are highly dependent on the principal members of our management staff, particularly our President and Chief Executive Officer, Chief Financial Officer and General Counsel. As a result of the staged wind-down of our business, it may be difficult for us to provide adequate incentives for these employees to remain employed with us. The loss of any of these employees could cause a material adverse effect on our ability to efficiently implement the staged wind-down of our business.

ITEM 2. PROPERTIES

The Company s headquarters are located in Norcross, Georgia and consist of a manufacturing and administrative facility totaling approximately 50,000 square feet of leased office and manufacturing space, including a 4,100 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. The lease for the property in Norcross, Georgia expires on December 31, 2005 and as part of the staged wind-down plan, we will be attempting to take actions that mitigate the costs of continued maintenance and utilization of the facility. The lease for the facility in Krefeld, Germany expires April 30, 2005, and will not be renewed.

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

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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 case will require the expenditure of significant time and resources.

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.

By settlement agreement, dated June 4, 2004, the Company settled the law suit filed in the U.S. District Court for the District of Connecticut against Scott Sacane, Durus Capital Management, LLC and Durus Life Sciences Master Fund, Ltd. Pursuant to the Settlement Agreement, the defendants filed amended Forms 4 with the Securities and Exchange Commission, correcting disclosure of the purchases and sales of the Company s Common Stock, and paid to the Company the sums of money received from the purchases and sales of the Company s Common Stock, which were short-swing profits under Section 16(b). The Complaint filed by Novoste was dismissed pursuant to a Stipulation of Dismissal, with prejudice, on June 18, 2004.

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

There were no matters submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2004.

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PART II

ITEM 5. MARKET FOR THE REGISTRANT S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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, 2005 was 87 excluding beneficial owners of shares that are registered in nominee or street name. The Company has not paid any cash dividends since its inception.

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, 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
Year Ended December 31, 2004		
March 31, 2004	$ 5.70	$ 3.11
June 30, 2004	$ 3.47	$ 2.48
September 30, 2004	$ 2.93	$ 1.55
December 31, 2004	$ 1.76	$ 1.29

On March 1, 2005, the last reported sale price for the Common Stock was $0.90.

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ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected financial data shown below for the fiscal years ended December 31, 2004, 2003 and 2002, and as of December 31, 2004 and 2003, 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, 2001 and 2000, and as of December 31, 2002, 2001 and 2000, 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,				
	2004	2003	2002	2001	2000
	(In thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Net sales	$ 23,268	$ 62,901	$ 69,030	$ 69,908	$ 6,530
Costs and expenses:					
Cost of sales	16,111	24,315	27,313	19,164	4,258
Impairment and related charges	9,349		6,900		
Research and development	4,633	11,986	13,300	12,756	17,119
Sales and marketing	12,558	19,485	26,875	34,654	15,651
General and administrative	8,036	8,237	8,335	9,324	6,321
Restructuring and other expenses				1,214	
Loss from operations	(27,419)	(1,122)	(13,693)	(7,204)	(36,819)
Other income	498	254	642	2,095	3,746
Net loss	$ (26,921)	$ (868)	$ (13,051)	$ (5,109)	$ (33,073)
Basic and diluted net loss per share (1)	$ (1.65)	$ (0.05)	$ (0.80)	$ (0.32)	$ (2.13)
Weighted average shares outstanding (1)	16,333	16,313	16,268	16,152	15,517
Consolidated Balance Sheet Data:					
Working capital	$ 25,753	$ 39,364	$ 30,496	$ 40,482	$ 53,742
Total assets	33,702	61,407	67,520	82,911	77,073
Long-term liabilities			5	203	401
Accumulated deficit	(162,223)	(135,302)	(134,434)	(121,384)	(116,275)
Total shareholders equity	26,454	53,244	52,765	64,728	67,042

(1) See note 1 to the Consolidated Financial Statements for an explanation of the method used to compute net loss per share.

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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. grew to approximately 400 by 2003, before declining to approximately 250 at December 31, 2004.

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 vascular brachytherapy 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.

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 a clinical trial in July; all of which adversely affected our financial performance. Fiscal year 2004 was equally challenging, as the drug-eluting stents proved to be more effective than anticipated and our revenue declined significantly, $23,268,000 as compared to $62,901,000 for the fiscal year 2003. To address the decline, in March 2004, Novoste announced a reduction in force to take an additional 87 positions out of the work force. On April 22, 2004, Novoste concluded an asset purchase agreement with Guidant Corporation, pursuant to which Novoste acquired information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant for the United States and Canada, as well as a five-year non-compete agreement. As a result, Novoste became the sole provider of coronary brachytherapy products (see Notes 7 and 13 to consolidated financial statements). As noted below, Novoste began an aggressive cost reduction program at the end of the first quarter of 2004 and initiated restructuring of operations in the United States in order to bring expenses in line with lower revenues. During the second quarter of 2004, Novoste consolidated U.S. operations into a single building, with the expectation of significantly lowering fixed costs for facilities. In the third quarter of 2004, we saw the benefit of the Guidant transaction as approximately 80 customers were added or reinstated, billings for servicing transfer devices increased and our net rate of decline in catheter sales slowed. However, Novoste has sustained losses for the past 6 fiscal quarters. We anticipate that we will incur additional losses in future periods and that we will continue to have negative cash flow from operations for the foreseeable future. We also expect that these losses and the negative cash flow will constitute a material use of our cash resources in 2005. At the end of 2004, Novoste concluded that the stream of funds to be generated by the Beta-Cath product line would not be sufficient to cover the carrying value of long-lived assets and recorded an impairment charge of $9,349,000 to reduce these assets to fair value.

As a result, we had a net loss for the year ended December 31, 2004 of $26,921,000, or $1.65 per share, with an accumulated deficit of approximately $162,223,000.

On February 22, 2005, we announced that our board of directors has determined that our vascular brachytherapy products business, which is our only business line, is no longer viable, and as a result, has authorized a staged wind-down of our business. On such date, we announced that, pursuant to the first stage of our wind down plan, we will reduce the U.S. workforce in the first quarter of 2005 by 52 employees, from 81 employees. Additionally, the Company notified all of its employees outside of the U.S. (16) that they will be terminated in accordance with their contracts and the relevant country s employment regulations in an effort to

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further reduce our costs. Our board has determined that this decision is necessary to preserve our cash resources and arises as a result of the continuing decline in revenue for our vascular brachytherapy products.

As previously disclosed, we have been actively seeking new product opportunities, as well as a merger, business combination or other disposition of our business or assets, due to the continuing challenges facing our vascular brachytherapy business. As part of our ongoing review of potential options, we retained an investment banking and strategic advisor, Asanté Partners LLC, in April 2004, to assist us in our efforts to identify and implement strategic and financial alternatives. If a suitable transaction resolving our future on acceptable terms does not become available in the relatively near term, we will need to consider other alternatives, which could include liquidation and dissolution.

As part of our review of potential strategic alternatives, we have received inquiries from, and have engaged in discussions with, companies potentially interested in a merger or business combination with us. Based on these inquiries and discussions, we cannot assure our shareholders that any such transaction will be successfully concluded. Further, even if such a transaction is successfully concluded, the value of the consideration that could be received by, or the transaction value to, our shareholders in such a merger or business combination could be less than the prices at which our common stock has recently traded.

If we were to liquidate and dissolve, we cannot predict when or if we would be able to make a distribution to our shareholders. However, in the event that one or more cash distributions were made after dissolution, we expect that the amount distributed after dissolution could be significantly lower than the prices at which our common stock has traded in the recent past, and there can be no assurance that such amount would equal the prices at which our common stock could trade in the future. Any distributions after dissolution would be reduced by cash expenditures during the staged wind-down of our business, and by the ultimate amounts paid in settlement of our liabilities. Prior to authorizing any distribution to shareholders after dissolution, our board of directors would need to make adequate provision to satisfy known and unknown claims against us, and our liability for such claims may extend for a substantial period of time in the future. As a result, there can be no assurance that we would have sufficient cash available to make any distributions to shareholders after dissolution. If we were to have sufficient remaining cash, a substantial period may elapse after dissolution before we would be able to make any such distribution to shareholders, and such distribution, if any, may be made in more than one installment over an extended period of time.

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, included in Item 15, discusses our significant accounting policies.

Asset Impairment

Novoste evaluates the carrying value of long-lived assets in accordance with the provisions of SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. SFAS No. 144 requires impairment losses to be recognized

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for long-lived assets used in operations when indicators of impairment are present and the estimated undiscounted cash flows are not sufficient to recover the assets carrying value. The impairment loss is measured by comparing the estimated fair value of the asset, usually based on discounted cash flows, to its carrying amount. Due to continuing declines in the Company s current and projected future revenues and cash flows, during 2004, the Company evaluated the recovery of its long-lived assets and recorded an impairment charge of $9,349,000 on long-lived assets, including property and equipment, radiation and transfer devices, and other assets (see Note 15 to consolidated financial statements).

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 through mutual negotiation and settlement.

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 after 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 other than in cases of product malfunction or shipping errors. In connection with the recall of 3.5F catheters in the third quarter of 2002 and subsequent relaunch in early 2003, the Company offered to exchange defective 3.5F catheters for 5.0F catheters until the redesigned 3.5F catheters were available, and agreed to take back any unused 5.0F catheters for redesigned 3.5F catheters upon re-launch of the new 3.5F catheters. The selling prices of the redesigned 3.5F and the 5.0F catheters were the same. 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. This revenue was recognized during 2003 as these exchanges occurred. Selling expenses of $200,000 relating to this revenue reserve were deferred, and were released as revenue was recognized. The cost of goods sold relating to this revenue reserve were deemed immaterial and therefore not deferred.

Radiation and Transfer Devices and Amortization of Costs

The Company retains ownership of the radiation source trains (RSTs) and transfer devices (TDs). 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 (see

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Note 6 to consolidated financial statements). 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.

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 were 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 results.

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. Based on this evaluation, the Company determined that an impairment and other related charges of $6,900,000 were warranted (see Note 15 to consolidated financial statements). As of December 31, 2003 the net book value of 5.0F assets was zero.

During 2004, the Company recorded a total impairment charge of $9,349,000 of which $3,443,000 related to radiation and transfer devices (see Note 15 to consolidated financial statements).

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 (see Notes 1 and 12 to consolidated financial statements).

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. Actual losses from uncollectible accounts are charged against the allowance when it is determined that the account cannot be collected (see Note 3 to consolidated financial statements).

Inventories

Novoste values its inventories at the lower of cost or market value on a first-in, first-out (FIFO) basis. Reserves 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

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conditions become 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 (see Note 4 to consolidated financial statements).

Intangible Assets

These assets consist of licenses, patents, and customer list acquired from Guidant. They are recorded at cost and amortized over the term of the license, life of the patent, or estimated life of the customer list. During the fourth quarter of 2004, the Company performed an impairment evaluation in accordance with the provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Based on this evaluation, the Company recorded a charge of $1,719,000 to reduce the fair value of these assets to zero (see Note 15 to consolidated financial statements).

RESULTS OF OPERATIONS

Comparison of Years Ended December 31, 2004 and 2003

Net Sales and Gross Margin

Net sales, cost of sales, and gross margin are comprised of the following (in thousands):

	Year Ended December 31,		
	2004	2003	Increase (decrease)
Net sales:			
United States	$ 19,391	$ 57,915	(66.5%)
Rest of World	3,877	4,986	(22.2%)
Total net sales	23,268	62,901	(63.0%)
Cost of sales	16,111	24,315	(33.7%)
Impairment charge	7,630		100.0%
Gross margin	$ (473)	$ 38,586	(101.2%)

Both the U.S. and international VBT markets were negatively affected by the introduction of drug-eluting stents. The international market, however, did not decline as much because drug-eluting stents are not as predominant in PTCA procedures outside of the United States.

Net sales decreased 63% to $23,268,000 for the year ending December 31, 2004, from $62,901,000 for the year ending December 31, 2003. Catheter unit volume in the U.S. declined 70% as drug-eluting stents have proven to be very effective in reducing in-stent restenosis. However, unit volume decline outside the U.S. was limited to 33% for the reasons mentioned above. The volume decline in the U.S. was somewhat offset by a 112% increase in revenue from service and lease agreements for radiation devices which was facilitated by the transaction with Guidant in April 2004 that made Novoste the sole source of VBT technology and provided a stronger marketing position from which to bill for these services. By comparison, our 2003 revenues also included $2,150,000 of revenue recognition when 3.5F catheters were exchanged for 5.0F catheters. (For discussion of the recall of our 3.5F catheters, see Note 1 to our consolidated financial statements included in this Form 10-K.) We expect that VBT usage and, correspondingly, sales of our VBT products will continue to decline in 2005, resulting in a future reduction in our revenues. In addition, given the Company announcement in February 2005 that the vascular brachytherapy business is no longer viable, and that the Company has announced a staged wind-down of the business, it is expected that revenues will be significantly reduced in 2005.

Stent revenue declined in Europe due to the presence of heavy competition from larger companies and with the introduction of DES. The sale of stents will be discontinued by the Company in the first quarter of 2005.

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Cost of sales for 2004 declined due to much lower unit volume and lower radiation device amortization as the 5.0F and many 3.5F radiation devices completed their amortizable life. Cost of sales does not decrease proportionally to sales due to higher fixed costs associated with excessive production and service capacity. In addition, $190,000 was recorded in 2004 related to royalty payments to Guidant in connection with purchase of their customer list, and $695,000 in stand-by fees were paid to our supplier of radiation source trains (AEA) for maintaining their production facility in the absence of demand from the Company. Cost of sales also increased $7,630,000 as a result of the impairment (and related write-down in the carrying value) of the long-lived assets related to the production process.

Operating Expenses

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

	Year Ended December 31,		
	2004	2003	Increase (decrease)
Operating expenses:			
Research and development	$ 4,633	$ 11,986	(61.3%)
Sales and marketing	12,558	19,485	(35.6%)
General and administrative	8,036	8,237	(2.4%)
Impairment charge	1,719		100.0%
Total operating expenses	$ 26,946	$ 39,708	(32.1%)

Research and Development Expenses. The 61% decline in research and development costs is due to reduced activity in product development and clinical trials. Clinical expenses declined by more than $4,018,000 due to the cessation of clinical trials and reduction of personnel. The product development department costs declined by $3,400,000 as in-house development was suspended and the technical staff reduced, being replaced by a modest outsourced development effort.

Sales and Marketing Expenses. Costs have declined mainly due to lower revenues and the variable costs associated with revenue and staffing levels, such as commissions, travel, marketing incentives and trade show participation. Costs for the U.S. sales force declined $6,300,000 as field sales personnel was reduced from 57 to 19. Other factors include fewer trade show activities and less travel than in 2003, when the 3.5F catheter system was relaunched, and a smaller in-house sales and marketing group supporting a reduced field personnel.

General and Administrative Expenses. The 2.4% net decline in 2004 was attributed to cost reduction initiatives including lower headcount and reduced legal fees associated with patent filings, offset by the compliance costs of Sarbanes-Oxley Section 404, investment banking fees, and retention payments for key employees.

Impairment Charge. This charge primarily relates to the unamortized portion of the customer list purchased from Guidant in April 2004. The list is part of the enterprise-wide group of long-lived assets, which are impaired due to insufficient discounted projected cash flow to recover their carrying value (see Note 15 to consolidated financial statements).

Other Income

Other income is as follows (in thousands):

	Year Ended December 31,		
	2004	2003	Increase (decrease)
Total other income	$ 498	$ 254	96.1%

The increase is primarily attributable to the increase in interest income as a result of higher interest rates compared to 2003, a shift to longer maturity investments which enjoy a higher interest rate, and to proceeds from the sale of assets which occurred when the company consolidated U.S. operations into a single building.

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Net Loss

Net loss and per share results are as follows (in thousands, except per share):

	Year Ended December 31,		
	2004	2003	Increase (decrease)
Net loss	$ (26,921)	$ (868)	$ (26,053)
Net loss per share basic and diluted	$ (1.65)	$ (0.05)	$ (1.60)

The increase in net loss is due to the rapid decline in revenues and the Company s inability to reduce costs proportionally. In addition, $9,349,000, or approximately 36% of the total, is the result of the impairment charge that reduced the carrying value of long-lived assets to fair value.

Comparison of Years Ended December 31, 2003 and 2002

Net Sales and Gross Margin

Net sales, cost of sales, and gross margin are comprised of the following (in thousands):

	Year Ended December 31,		
	2003	2002	Increase (decrease)
Net sales:			
United States	$ 57,915	$ 64,746	(10.6%)
Rest of World	4,986	4,284	16.4%
Total net sales	62,901	69,030	(8.9%)
Cost of sales	24,315	27,313	(11.0%)
Impairment charge		6,900	(100.0%)
Gross margin	$38,586	$ 34,817	10.8%

Net sales declined 8.9% to $62,901,000 for the year ended December 31, 2003, from $69,030,000 for the year ended December 31, 2002. The revenue decline is due to a 12% reduction in the sales of catheters and a 73% reduction in lease revenue for radiation devices. The decline in catheters was the result of lower utilization of VBT in treating coronary patients attributable to the introduction of drug-eluting stents into the U.S. market in April 2003. 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. The sale of stents contributed $620,000, or 13%, to our international revenues.

Cost of sales for 2003 returned to a level more in line with historical results as compared to 2002, which was unusually high due to the $6,900,000 impairment charge, or 10% of sales. (For a discussion of this impairment charge, see Note 1 to the Consolidated Notes to the Financial Statements included in this Form 10-K). 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 became 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 as a percent of revenue, as a result of the cost reduction actions taken above.

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Operating Expenses

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

	Year Ended December 31,		
	2003	2002	Increase (decrease)
Operating expenses:			
Research and development	$ 11,986	$ 13,300	(9.9%)
Sales and marketing	19,485	26,875	(27.5%)
General and administrative	8,237	8,335	(1.2%)
Total operating expenses	$ 39,708	$ 48,510	(18.1%)

Research and Development Expenses. The decline was mainly due to lower engineering and operating costs of $1,800,000 from restructuring of the engineering and product development functions. This decline was offset by an increase of $540,000 for clinical studies on potential new products.

Sales and Marketing Expenses. Costs declined mainly due to lower revenues and the variable costs associated with revenue, such as commissions, travel, marketing incentives and trade show participation. Costs for the U.S. sales force declined $3,954,000. Other factors include fewer trade show activities than in 2002, when the 3.5F catheter system was introduced, and additional marketing costs decline of $1,497,000. The closing of the sales office in Brussels in March 2002 and a reduced number of field personnel lowered expense by $1,274,000 in Europe.

General and Administrative Expenses. The decline of 1.2% was attributed to the completion of a computer systems upgrade project and to ongoing cost reduction efforts in 2003.

Other Income

Other income is as follows (in thousands):

	Year Ended December 31,		
	2003	2002	Increase (decrease)

Total other income	$ 254	$ 642	(60.4%)

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.

Net loss

Net loss and per share results are as follows (in thousands, except per share):

	Year Ended December 31,		
	2003	**2002**	**Increase (decrease)**
Net loss	$ (868)	$ (13,051)	$ 12,183
Net loss per share basic and diluted	$ (0.05)	$ (0.80)	$ 0.75

The loss was moderated due to no repeat of the impairment charge of 2002, the recognition of $2,150,000 in catheter revenue when the 3.5F product exchange was completed, and cost reduction efforts.

LIQUIDITY AND CAPITAL RESOURCES

During the year ended December 31, 2004, Novoste cash and cash equivalents decreased to $19,082,000 from $33,177,000 at the end of 2003. Of this decrease of $14,095,000, there was $6,300,000 used to fund operating activities, and net cash used in investing activities was $7,876,000.

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Operating activities

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

	Year Ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	$ (26,921)	$ (868)	$ (13,051)
Depreciation and amortization of property, equipment and intangibles	3,706	3,295	3,125
Depreciation of radiation and transfer devices	4,124	8,606	9,241
Impairment charge	9,349		5,065
Other non cash items	(168)	(265)	758
Accounts receivable	3,502	2,043	9,326
Inventory	1,091	1,521	(85)
Prepaid expenses and other current assets	(290)	508	36
Other assets	742	890	(285)
Accounts payable	(33)	(753)	(2,033)
Accrued expenses	(3,125)	(3,527)	(1,001)
Unearned revenue	1,723	(2,258)	(387)
Net cash (used in) provided by operating activities	$ (6,300)	$ 9,192	$ 10,709

The cash trend in 2004 is consistent with patterns expected of a declining business. Working capital is generating funds as inventory and receivables decline. Non-cash items such as depreciation charges mitigate losses, as capital assets are not replaced.

For the year ended December 31, 2004, a loss due to the decline in revenue could not be offset by the contraction of working capital and non-cash items, and $6,300,000 in cash was used to fund operations. The declines in receivables generated $3,502,000, as collections occurred faster than revenue replaced them. Inventory declined as the reduced business volume eliminated the need for replacing items sold and used in service. The most significant use of working capital is the pay-down of accruals and payables. Depreciation on radiation devices is declining because many of the devices have reached their depreciable life and are not being replaced. Depreciation on property and equipment is also declining because many of the production assets purchased when the company began commercial operations in 1999 and 2000 have reached their depreciable life. For 2004, amortization increased due to the customer list acquired from Guidant in April, which was being amortized over 2 years. In addition, during 2004 the Company recorded an impairment charge of $9,349,000 on long-lived assets including property and equipment, radiation and transfer devices, and other assets (see Note 15 to consolidated financial statements).

The years 2002 and 2003 generated operating cash for the same reasons described above, but because the losses were not as large and the contraction of working capital items and non-cash charges were able to offset the losses.

Investing activities

Net cash used by investing activities for the year ended December 31, 2004, was $7,876,000 of which $3,753,000 was shifted to longer term maturities of available-for-sale securities to improve yields; $517,000 was used for purchase of property and equipment, with most of this expenditure related to leasehold improvements incurred with the consolidation of U.S. operations into one location; $2,500,000 was used to purchase the customer list from Guidant; and $1,106,000 was used for the purchase of additional radiation and transfer devices, but at a lower level than 2003, because the number of customer sites declined and transfer device returns from closed sites were adequate to meet service needs.

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Financing activities

Novoste s financing activities include the purchase of treasury stock, equity offerings and borrowings and repayments of capital leases. The only financing activity in 2004 was the receipt by Novoste of $15,000 from the exercise of stock options and sales of our common stock to employees under the stock purchase program. Prior year financing activities for the year ended December 31, 2003 provided $476,000 in net from the issuance of common stock offset by the purchase of treasury stock and repayment of capital lease obligations.

Liquidity

The Company s principal source of liquidity at December 31, 2004 consisted of cash, cash equivalents and short-term investments in the amount of $29,060,000, compared to $39,402,000 as of December 31, 2003.

In August 2001, the Company obtained a $10 million revolving line of credit with a financial institution (lender). This agreement was extended from time to time. In May 2004, Novoste replaced its working capital loan agreement and obtained a $5,000,000 revolving line of credit with the same financial institution (lender). On December 22, 2004, Novoste and the lender mutually agreed to terminate the line of credit, there being no foreseeable need for the revolving credit line and the small borrowing base that resulted from declining business. At December 31, 2004, Novoste had no outstanding borrowings, but had $75,000 in outstanding letters of credit (see Note 9 to consolidated financial statements).

On February 22, 2005, the Company announced a staged wind-down of the VBT business. The Company believes that existing cash will be sufficient to meet its working capital, financing and capital expenditure requirements through the execution of the wind-down.

Commitments

At December 31, 2004, the Company had commitments to purchase $221,000 in inventory components of the Beta-Cath System and other supplies.

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 development 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 trains by using the development equipment to produce the smaller diameter radiation source 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 Novoste. Annual minimum purchase commitments and pricing guidelines have been established extending to 2006 and are reflected below on the table of contractual obligations. These estimates are subject to negotiation and settlement with AEA. During 2004, Novoste did not reach the minimum purchase commitment level for product and incurred an expense in cost of sales of $695,000 for this shortfall. At the termination of the agreement, Novoste is obligated for costs associated with decommissioning the production facility and $621,000 has been accrued for this purpose and is being expensed in cost of sales in accordance with SFAS 143, *Accounting for Asset Retirement Obligation*.

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 guaranteed minimum annual payments to Bebig in varying amounts. All product purchases are credited against the annual guaranteed payment. In the event that the Company did not purchase

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product to exceed the annual guaranteed payment, the deficiency was due and payable to Bebig within thirty days after the end of each one-year contract period. During 2004, Novoste did not reach the minimum purchase commitment level. This shortfall had been accrued as part of the 2002 impairment evaluation related to the 5.0F System (see Note 15 to the consolidated financial statements). Novoste paid $681,000 to cover the purchase shortfall. The final purchase commitments of $250,000 will be paid in the first quarter of 2005 and is fully accrued as of December 31, 2004. There is an obligation of $250,000 to reimburse Bebig for expenses associated with decommissioning the production line which is also fully accrued as of December 31, 2004. Payment of this obligation will be completed by June 19, 2005, the expiration date of this agreement.

On January 31, 1996, the Company 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 $206,000, $585,000, and $668,000, in 2004, 2003 and 2002, respectively, and have been expensed in cost of sales.

On January 30, 1996, the Company entered into a license agreement whereby Emory University assigned its claim to certain technology to the Company for royalties based on net sales (as defined in the agreement) of products derived from such technology, subject to certain minimum royalties. After the first commercial sale of royalty bearing products by Novoste, minimum royalties were due to Emory University in the following amounts: year 2 after the first commercial sale $10,000; year 3 $15,000; year 4 $25,000; and years 5-10, $50,000 per year. The royalty agreement term is consistent with the life of the related patent and applies to any assignments of the patent technology to a third party. Royalty fees to Emory University aggregated $468,000, $1,192,000, and $1,378,000, in 2004, 2003 and 2002, respectively, and have been expensed in cost of sales.

On April 22, 2004, Novoste signed an asset purchase agreement with Guidant pursuant to which Novoste would acquire information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant in the United States and Canada. Novoste paid the sum of $2,500,000 to Guidant at the signing of the transaction and has agreed to pay 5% on its net sales to customers on the Guidant customer list that transition to Novoste s products for a period of six months after April 22, 2004. After this six month transition period, Novoste will pay an additional 5% on of all vascular brachytherapy products in the U.S. and Canada, up to an additional payment of $4,000,000 (see Notes 7 and 13 to consolidated financial statements). Under this agreement, Guidant has earned $227,000 in additional payments during 2004.

As of December 31, 2004, we had contractual obligations as follows (in thousands):

	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual Obligations					
Operating Leases	$ 414	$ 369	$ 45	$	$
Purchase Obligations	1,956	1,311	645		
Total	$ 2,370	$ 1,680	$ 690	$	$

Approximately $1,735,000 of the purchase obligations listed above relates to purchase contracts denominated in Euros. This amount was derived from converting such purchase obligations by using a December 31, 2004 conversion rate of $1.36 USD to 1 Euro. As noted above, some of these purchase obligations extend to 2006 and the actual settlement amount may be different from the amount presented based on the conversion rate as of December 31, 2004.

OFF-BALANCE SHEET ARRANGEMENTS

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

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RECENT ACCOUNTING PRONOUNCEMENTS

In December 2004, the FASB issued FASB Statement No. 123(R) (revised 2004), *Share Based Payment*. Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. The revised Statement generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25, *Accounting for Stock Issued to Employees*, which was permitted under Statement 123, as originally issued. The revised Statement requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements. Statement 123(R) is effective for the Company after June 15, 2005 (i.e., for our third quarter 2005). All public companies must use either the modified prospective or the modified retrospective transition method. We are currently evaluating the impact of adoption of this pronouncement, which must be adopted in the third quarter of fiscal year 2005.

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, but we believe these risks are immaterial due to the short-term nature of these investments. 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, 2004, the Company had $19,082,000 in cash and cash equivalents with a weighted average interest rate of 1.82% and $9,978,000 in available-for-sale investments with a weighted average interest rate of 2.56%. 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%.

Foreign Currency Risk

International revenues from the Company s foreign direct sales and distributor sales comprised 16.7%, 7.9%, and 6.2% of total revenues for the years ended December 31, 2004, 2003 and 2002, 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, 2004.

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

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profitability. During 2004, the Euro increased against the dollar to 1.36 from 1.25, a 9% increase. This resulted in a $95,000 translation adjustment, which is included with Other Comprehensive Income.

Approximately $1,735,000 of our purchase obligations listed under Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations relate to purchase contracts and $659,000 of future expenses are denominated in Euros. These amounts were derived from converting the purchase obligations using a December 31, 2004 conversion rate of $1.36 USD to 1 Euro. As noted above, some of these obligations extend to the end of 2006 and the actual settlement amount may be different from the amount that is presented based on the conversion rate as of December 31, 2004.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements, with the report of the independent registered public accounting firm, 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

None.

ITEM 9A. CONTROLS AND PROCEDURES

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 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 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.

Management s Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control Integrated Framework , our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Ernst & Young LLP, an independent registered public accounting firm that audited our financial statements included in this Annual Report on Form 10-K, has issued an attestation report on management s assessment of our internal control over financial reporting. Such attestation, which expresses unqualified opinions on management s assessment and on the effectiveness of our internal control over financial reporting as of December 31, 2004, is included in Item 15 under the heading Report of Independent Registered Public Accounting Firm On Internal Control.

Changes in Internal Control. During the fourth quarter of fiscal year 2004, 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.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

DIRECTORS OF NOVOSTE

Class III Directors Whose Terms Expire in 2005

Thomas D. Weldon, age 49. Mr. Weldon co-founded Novoste and has served as a director since May 1992, when we began operations. In June 1998, Mr. Weldon became Chairman of Novoste. From May 1992 through March 1999, Mr. Weldon also served as Chief Executive Officer of Novoste. He again served as Chief Executive Officer of Novoste, on an interim basis, from January to October 2002, during our search for a new Chief Executive Officer. In April 1999, he co-founded The Innovation Factory, a medical device venture, where he currently serves as Chairman. Mr. Weldon co-founded and was President, Chief Executive officer and a Director of Novoste Puerto Rico Inc., a manufacturer of disposable cardiovascular medical devices, from 1987 to May 1992, prior to its sale. Previous responsibilities included management positions at Arthur Young & Company and Key Pharmaceuticals. Mr. Weldon received a B.S. in Industrial Engineering from Purdue University and an M.B.A. in Operations and Systems Management from Indiana University.

Charles E. Larsen, age 53. Mr. Larsen co-founded Novoste and has served as a director since May 1992, when we began operations. Currently, Mr. Larsen is the Chief Executive Officer and a director of The Innovation Factory, a medical device venture that he co-founded in 1999. As an employee of Novoste, he served as Chief Operating Officer from 1992 until 1997, and then as Senior Vice President and Chief Technical Officer until 1999. Mr. Larsen co-founded and was Vice President and Director of Novoste Puerto Rico, Inc. from 1987 to May 1992. From 1983 through 1987, Mr. Larsen was a manager of manufacturing engineering at Cordis Corporation. Mr. Larsen received a B.S. in Mechanical Engineering from New Jersey Institute of Technology.

Class I Directors Whose Terms Expire in 2006

J. Stephen Holmes, age 61. Mr. Holmes has served as a director of Novoste since October 1992. He became President of Teleflex Medical, N.A., a medical device company, in February 1998. He retired from Teleflex Medical in August 2003. For two years prior thereto, Mr. Holmes was Executive Manager of Saber Endoscopy, LLC, a medical device company he formed in February 1996. From 1992 through 1995, Mr. Holmes was a private investor, having founded several start-up companies from 1979 through 1992, including Adler Instrument Company, Inc., SOLOS Ophthalmology, Inc. and SOLOS Endoscopy, Inc., which he founded in 1982, 1988 and 1990, respectively, and in which he sold his interests in 1988, 1991 and 1991, respectively. Mr. Holmes received a B.S. in Marketing from the University of Evansville.

Stephen I. Shapiro, age 60. Mr. Shapiro has served as a director of Novoste since October 1996. Mr. Shapiro previously served as a director of Novoste from August 1995 until his resignation in March 1996. Since 1999, he has been employed with two venture capital firms, Advanced Technology Ventures and Galen Associates. Beginning in 1982, he was a Managing Principal of The Wilkerson Group, now integrated into IBM s healthcare consulting group with clients in the health care industry. From 1970 to 1982, Mr. Shapiro held a variety of technical management and strategic planning positions with Union Carbide Clinical Diagnostics and Becton Dickinson and Company. Mr. Shapiro received a B.S. degree in Chemical Engineering from the Massachusetts Institute of Technology and a M.S. degree in Chemical Engineering from the University of California at Berkeley.

William E. Whitmer, age 71. Mr. Whitmer has served as a director of Novoste since October 1992. He was also a director of Interland Inc., a NASDAQ-listed company, from March 2000 until the company s merger with Micron Electronics, Inc. Mr. Whitmer is a Certified Public Accountant and management consultant. From 1989 until 1992, he was a partner of Ernst & Young, having served as the Associate Managing Director of that firm s

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southern United States management consulting group. From 1968 through 1989, Mr. Whitmer was a partner of Arthur Young & Company, having served as the Managing Partner of its East and Southeast United States regions of the management consulting practice from 1975 through 1989. Mr. Whitmer received a B.A. in Economics from Denison University.

Class II Directors Whose Terms Expire in 2007

Alfred J. Novak, age 57. Mr. Novak was elected by the Board of Directors to the position of a director of Novoste on October 16, 2002; at the time he was appointed and joined Novoste as Chief Executive Officer. 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 ProRhythm, Inc., a start-up medical device company. 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. Mr. 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.

Judy Lindstrom, age 60. Ms. Lindstrom was elected a director of Novoste in June 2002, by the Board of Directors, to fill a vacancy in the Class II director class. Ms. Lindstrom is currently Chief Operating Officer of Portland Orthopaedics, a medical device manufacturer which produces a unique, proprietary hip transplant. She has held this position since October 2001. Prior to her position with Portland Orthopaedics, from March 1998 to October 2001, Ms. Lindstrom was a consultant and owner of J.L. International, a consulting firm specializing in international medical device marketing and operations. From August 1996 to February 1998, Ms. Lindstrom was employed by Wright Medical Technology, Inc., serving as that company s Executive Vice President of Global Sales and Marketing from June 1997 to February 1998, and its Executive Vice President, International from August 1996 to June 1997. Ms. Lindstrom served as a director on the board of directors of Everest Medical Corporation from 1991 to 1995 and as a member of the board of directors of the Health Industry Manufacturers Association in 1994. Ms. Lindstrom received a diploma in Registered Nursing from DePaul Hospital in Norfolk, Virginia and earned a B.S. degree in Biology from William and Mary College in Williamsburg, Virginia.

EXECUTIVE OFFICERS OF NOVOSTE

Our executive officers as of December 31, 2004, and their ages as of such date, were as follows:

Name	Age	Position
Alfred J. Novak	57	President and Chief Executive Officer
Andrew Green*	36	Vice President, Scientific Affairs
Daniel G. Hall	58	Vice President, Secretary and General Counsel
Adam G. Lowe	42	Vice President, Operations
Subhash C. Sarda	55	Chief Financial Officer, Vice President, Finance, and Controller
Susan D. Smith*	55	Vice President, Human Resources
Robert N. Wood, Jr.*	51	Vice President, Sales and Marketing

* In connection with the staged wind-down of the Company s vascular brachytherapy products business, this executive officer has ceased employment with the Company.

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 ProRhythm, Inc., a start-up medical device companies. Between 1996 and 1998 Mr. Novak

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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. Mr. 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.

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, and 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 March 2004 to present he has served as Vice President, Operations. 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 served as Acting Chief Financial Officer beginning in August 2003. In February 2004, he was promoted to the position of Vice President, Finance and continued to be responsible for the duties of Controller and Acting Chief Financial Officer until December 2004 when he was promoted to the position of Chief Financial Officer. Prior to joining Novoste Corporation, Mr. Sarda worked in a number of multi-national companies with management 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.

AUDIT COMMITTEE

The Board of Directors has a standing Audit Committee. The Audit Committee is composed entirely of independent directors as such term is defined in Section 10A(m)(3) of the Securities Exchange Act of 1934. The Audit Committee is currently comprised of William E. Whitmer, J. Stephen Holmes and Judy Lindstrom. The Board of Directors has determined that Mr. Whitmer is an audit committee financial expert, as that term is defined in Item 401(h) of Regulation S-K, and independent for purposes of current listing standards of The NASDAQ Stock Market and Section 10A(m)(3) of the Securities Exchange Act of 1934.

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CODE OF ETHICS

The Board of Directors has adopted a code of business conduct and ethics that applies to all of the Company s employees, officers and directors. The text of the code of business conduct and ethics is posted on the Company s Internet website (http://www.novoste.com).

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16 of the Exchange Act requires that officers, directors and holders of more than 10% of our Common Stock (collectively, reporting persons) file reports of their trading in Novoste equity securities with the SEC. Based on a review of Section 16 forms filed by the reporting persons during the last fiscal year, Novoste believes that all reporting persons complied with all applicable Section 16 requirements for Form 3, Form 4 and Form 5 filings during 2004.

ITEM 11. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION AND OTHER INFORMATION

The following table sets forth a summary of the compensation paid or accrued by us during fiscal years 2004, 2003 and 2002 to (1) our Chief Executive Officer and (2) the four other most highly compensated executive officers who were serving as executive officers at the end of fiscal year 2004 and whose compensation during fiscal year 2004 exceeded $100,000 (collectively, the Named Executive Officers):

Summary Compensation Table

		Annual Compensation			Long-Term Compensation (2)		
Name And Principal Position	Year	Salary	Bonus (7)	Other Annual Compensation (1)	Restricted Stock Awards	Common Stock Underlying Options (3)	All Other Compensation (4)
Alfred J. Novak	2004	$ 429,441	$ 489,538	$ 29,487(6)	$	200,000	$ 5,333
President and CEO (5)	2003	350,000	123,452	72,156(6)		8,700	4,671
	2002	64,615	6,417			700,000	
Robert N. Wood, Jr.	2004	271,296	222,370			75,000	4,750
VP Marketing & Sales	2003	223,649	56,612			8,700	4,280
	2002	206,730	17,655			26,250	41,196

Daniel G. Hall	2004	197,772	170,675	0	3,955
VP and Corporate	2003	186,810	47,287	8,700	2,612
Secretary & General Counsel	2002	170,312	14,747	23,125	24,416
Adam G. Lowe	2004	180,761	154,634	0	3,268
VP Quality Assurance	2003	167,228	42,330	8,700	3,015
	2002	153,321	13,201	19,375	24,873
Andrew M. Green	2004	171,644	145,975		3,432
VP Scientific Affairs	2003	141,385	32,918	75,000	2,807
	2002	112,019	10,313	19,700	2,240

(1) Except as provided below, we did not pay any other annual compensation to the Named Executive Officers during the fiscal years 2004, 2003 and 2002.

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(2) Novoste did not grant any stock appreciation rights or make any long-term incentive payouts to the Named Executive officers during the fiscal years 2004, 2003 and 2002.
(3) See Stock Options below for the exercise price and vesting terms of the options granted.
(4) Includes employer contributions to the defined contribution 401(k) plan during fiscal years 2004, 2003 and 2002 and the deferred compensation plan in fiscal year 2002.
(5) Mr. Novak joined Novoste as President and Chief Executive Officer on October 16, 2002.
(6) Consists of payments for Mr. Novak s apartment and airfare fees paid by us under the terms of Mr. Novak s employment agreement, dated October 8, 2002.
(7) Bonus compensation for 2004 includes payments of executive retention bonuses, as described below under the caption Executive Retention Bonus Agreements.

Stock Options

The following table sets forth certain information concerning options granted in fiscal year 2004 to the Named Executive Officers named in the Summary Compensation Table.

Option Grants in Fiscal Year 2004

Name	Number of Securities Underlying Options Granted (1)	% of Total Options Granted to Employees in Fiscal Year 2004	Exercise Price Per Share (2)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (3) 5%	10%
Alfred J. Novak	200,000	22.6	$ 2.90	7/15/2014	$ 364,758.88	$ 924,370.63
Robert N. Wood, Jr.	75,000	8.5	2.90	7/15/2014	$ 136,784.58	$ 346,638.99
Daniel G. Hall	75,000	8.5	2.90	7/15/2014	$ 136,784.58	$ 346,638.99
Adam G. Lowe	75,000	8.5	2.90	7/15/2014	$ 136,784.58	$ 346,638.99
Andrew M. Green	75,000	8.5	2.90	7/15/2014	$ 136,784.58	$ 346,638.99

(1) Unless otherwise noted, each grant consists of ten-year options granted under the 2001 Stock Plan, exercisable cumulatively at the annual rate of one quarter of the number of underlying shares, commencing one year from the date of grant. All options become fully exercisable upon a change of control (as defined in the option agreements for each grant).
(2) The exercise price indicated was the fair market value of a share of our Common Stock on the date of grant.
(3) Amounts reported in this column represent hypothetical values that may be realized upon exercise of the options immediately prior to the expiration of their term, assuming the specified compounded rates of appreciation of our Common Stock over the term of the options. These numbers are calculated based on rules promulgated by the SEC. Actual gains, if any, in option exercises are dependent on the time of such exercise and the future performance of our Common Stock.

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Option Exercises and Holdings

The following table sets forth certain information concerning the number and value realized of options exercised during fiscal year 2004, and the number and value of unexercised options held at December 31, 2004 by the Named Executive Officers.

Option Exercises in Last Fiscal Year and Fiscal Year End Option Values

Name	Shares Acquired on Exercise	Value Realized	Number of Unexercised Options at December 31, 2004		Value of Unexercised In-the-Money Options at December 31, 2004 (1)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Alfred J. Novak			344,350	564,350	$	$
Robert N. Wood, Jr.			89,038	85,912	$	$
Daniel G. Hall			76,694	85,131	$	$
Adam G. Lowe			110,382	84,193	$	$
Andrew M. Green			48,200	93,600	$	$

(1) Based on the closing sale price of our Common Stock on The NASDAQ National Market as of December 31, 2004 ($1.71 per share) minus the applicable exercise price.

Executive Termination Agreements

In May 2003, we entered into amended and restated termination agreements with our executive officers (including the Named Executive Officers), which provide for benefits in the event of a termination of an executive officer after a change in control of Novoste. The termination agreements have an initial term from the date of execution of the termination agreements through December 31, 2003. After the initial term, the termination agreements are automatically extended each January 1 thereafter for one-year terms, unless notice not to extend the agreement is given not later than 12 months prior to such January 1. If a change in control (as defined in the termination agreement) occurs during the term, the termination agreement extends for 24 months even if such notice not to extend is given. Each executive officer who has entered into a termination agreement has agreed that following the termination of employment, if any, of such executive officer, he or she will be subject to a one-year non-compete and non-solicitation agreement with us.

Upon a change in control of Novoste and the subsequent termination of an executive officer without cause or for good reason, the executive officer will receive benefits including, but not limited to, the following: a severance payment equal to three times (or, in the case of executive officers who have served for two or less full years as an executive officer of Novoste, two times) his or her annual salary and bonus, as calculated pursuant to the terms of the termination agreement; a pro-rata portion of his or her target bonus for the year in which the change in control occurs; total health care benefits for 18 months; the use of office space or outplacement services for six months; and reimbursement of specified legal fees and expenses. In the event that any payments made by us to an executive officer in connection with the change in control would be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code), we are obligated to make whole the executive officer with respect to such excise tax.

Executive Retention Bonus Agreements

In April 2004, we entered into executive retention bonus agreements with our executive officers (including the Named Executive Officers), which provide for benefits to the executive officers for continued loyalty to Novoste during its restructuring period. The retention agreements are in effect from April 1, 2004 until December 31, 2005. Under the retention agreements, the executive officers will continue to perform the duties and responsibilities that are commensurate with each executive officer s position and will perform such other duties as we may reasonably require of the executive officers. The executive officers will also continue to devote their best efforts and full business time and attention to the performance of services customarily incident to each

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executive officer s position and to such other services as we may request. Each executive officer was or is entitled to receive the following retention bonus payments:

Mr. Novak received $333,350 for remaining in our employ through December 31, 2004 and will be entitled to receive $166,675 if he remains in our employ through March 31, 2005 (payable on the first pay date after March 31, 2005).

Mr. Wood received $166,675 for remaining in our employ through December 31, 2004 and was entitled to receive $83,350 for remaining in our employ through March 31, 2005. Mr. Wood ceased employment with Novoste in March 2005 and received a pro rated bonus payment of $58,345 for his retention as an employee during a portion of the quarterly period ending March 31, 2005.

Mr. Hall received $124,550 for remaining in our employ through December 31, 2004 and will be entitled to receive $62,275 if he remains in our employ through March 31, 2005 (payable on the first pay date after March 31, 2005).

Mr. Lowe received $111,500 for remaining in our employ through December 31, 2004 and will be entitled to receive $55,730 for remaining in our employ through March 31, 2005 (payable on the first pay date after March 31, 2005).

Mr. Green received $104,500 for remaining in our employ through December 31, 2004 and was entitled to receive $52,250 for remaining in our employ through March 31, 2005. Mr. Green ceased employment with Novoste in March 2005 and received a pro rated bonus payment of $36,575 for his retention as an employee during a portion of the quarterly period ending March 31, 2005.

With respect to Mr. Novak, his employment will continue to be terminable as described in the employment agreement between us and Mr. Novak, dated October 8, 2002, which agreement is described in greater detail below. If Mr. Novak is terminated without cause (as such term is defined in his employment agreement), he will receive benefits as set forth in the employment agreement. With respect to the other executive officers, their employment will continue to be terminable at-will. If we terminate an executive officer without cause (as such term is defined in the retention agreements) between March 31, 2005 and December 31, 2005, the executive officer will receive a severance package equal to 52 weeks salary at the executive officer s rate of base pay on the date of termination. If we terminate an executive officer without cause before December 31, 2005, we will pay the executive officer a prorated amount of the bonus that he would have been entitled to, based on the number of days he was employed by us during the year of termination. These payments are subject to such executive officer s execution and non-revocation of a release agreement referred to in the retention agreements. Messrs. Wood and Green ceased being employed by Novoste in March 2005. As a result, they each received a pro rated bonus payment, as further described above, for their retention as Novoste employees during a portion of the quarterly period ending March 31, 2005. In addition, Messrs. Wood and Green each received a severance package equal to 52 weeks salary at their respective base pay rates on their respective dates of termination.

Executive Employment Agreement

On October 8, 2002, we entered into an employment agreement with Mr. Novak which set forth the terms and conditions of Mr. Novak s employment as our chief executive officer. The employment agreement provides that, as compensation for Mr. Novak s services, we will pay a base salary of at least $350,000 per annum (with Mr. Novak s performance to be reviewed annually by our board of directors) and grant a ten-year non-incentive stock option to purchase an aggregate of 700,000 shares of our Common Stock, at an exercise price equal to the fair market value per share of the stock on the day of grant, upon the terms and conditions (including vesting schedules) as set forth in stock option agreements between Mr. Novak and us. Mr. Novak is also entitled to participate in our discretionary annual incentive cash bonus plan for executive officers, established to reward participating individuals for their contribution to the achievement of key annual corporate objectives approved by the board of directors. The employment agreement also provides that we will provide (1) a company-paid apartment for Mr. Novak s use and pay all expenses to the apartment including, rent, utilities, furniture rental up to $3,500 per month, (2) airfare for weekly visits to his family and (3) health, life, disability or other insurance

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plans, retirement plans, 401(k) plans, stock purchase plans and all other employee benefit plans that are offered by us, subject to the terms and conditions of those plans.

Mr. Novak s employment may be terminated at any time by us:

- for cause;
- if a majority of our board of directors (excluding Mr. Novak if he is then a director) gives a vote of no confidence based upon the nature or manner of the performance of his duties (which we refer to as unsatisfactory performance);
- upon 30 days prior written notice to Mr. Novak, if terminated without cause or unsatisfactory performance; or
- upon death or permanent disability.

Mr. Novak may also terminate his employment at any time for good reason or upon 90 days prior written notice to us without good reason.

If Mr. Novak s employment is terminated for cause, unsatisfactory performance, death or permanent disability, or by him without good reason, he (or his estate, as the case may be) will be entitled to be paid any accrued but unpaid salary earned by him through the date of his termination. If Mr. Novak s employment is terminated by us without cause or unsatisfactory performance (other than by reason of death or permanent disability, or by him for good reason, he will be entitled to (1) receive all accrued but unpaid salary earned through the date of termination, (2) receive a lump sum cash severance payment on the termination date equal to two times his annualized includable compensation, taking as a base period the two most recent taxable years ending before the termination date, and (3) accelerate the vesting of options for up to 400,000 shares of Common Stock from the initial option grant described above so that they become fully vested and exercisable on the termination date.

Compensation of Directors

Directors who are employees of Novoste do not receive additional compensation for serving on the Board of Directors or its committees. A non-employee director is paid a fee of $4,000 for each Board meeting attended. Each director who also serves on a committee is paid $1,000 for each committee meeting attended; the director who is a committee Chairperson receives a fee of $2,000 per meeting. There is no compensation for attendance at a scheduled Board or committee meeting to a director who attends such a meeting only by telephone. Compensation for scheduled telephonic meetings of the Board or any committee will be compensated at one-half of the established Board or committee attendance fee.

The Board of Directors established an annual retainer for the Chairman of the Board of Directors in the amount of $26,000, payable to the Chairman on the first day of each calendar year, and a retainer for the Chairman of the Audit Committee in the amount of $24,000 per year. In addition, in June 2004, the Board of Directors granted each of its non-employee directors, as partial compensation for director services rendered in 2004, a four-year incentive stock option to purchase 8,000 shares of our Common Stock at an exercise price of $2.96 per share, the closing market price of our Common Stock on The NASDAQ National Market on the grant date. All of these options become exercisable in quarter installments on each one-year anniversary after the grant date. Vesting of these options ceases on the date the option holder ceases to serve as a

director. The Chairman of the Board of Directors was granted 12,000 shares of our Common Stock at the same exercise price and on the same terms.

Compensation Committee Interlocks and Insider Participation

The members of the Stock Option and Compensation Committee during fiscal year 2004 were Dr. Donald C. Harrison, who resigned from our Board of Directors as of February 11, 2004, Ms. Lindstrom and Mr. Shapiro. Mr. Holmes became a member of the Stock Option and Compensation Committee after Dr. Harrison s resignation and served on that committee for the remainder of 2004. No member of the Stock Option and Compensation Committee has ever been an officer or employee of Novoste (or any of its subsidiaries), and no compensation committee interlocks existed during fiscal year 2004.

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ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

AND RELATED SHAREHOLDER MATTERS

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information about stock options outstanding and shares available for future awards under all of Novoste s equity compensation plans. The information is as of December 31, 2004. Novoste has not made any grants outside of its equity compensation plans.

Novoste currently has stock options outstanding which were granted from three plans approved by our shareholders, the Novoste Corporation Employee Equity Plan, the Novoste Corporation Non-Employee Stock Option Plan and the Novoste Corporation 2001 Stock Plan and two plans which were not approved by our shareholders, the Novoste Corporation 2002 Broad-Based Stock Plan and the 2002 Chief Executive Officer Stock Option Plan.

The Novoste Corporation Employee Equity Plan and the Non-Employee Stock Option Plan have been terminated in accordance with each plan s terms and there are, therefore, no shares available for future option grant under those plans. The 2002 Chief Executive Officer Plan was created specifically for providing a retention incentive when Novoste hired a new Chief Executive Officer in October 2002. There are no additional shares available for grant under that plan. Novoste does not have any warrants or stock appreciation rights outstanding under our equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	2,465,616	$ 8.3698	141,900
Equity compensation plans not approved by security holders	810,088	4.3751	82,912
Total	3,275,704	$ 7.3819	224,812

PRINCIPAL HOLDERS OF VOTING SECURITIES

Name of Beneficial Owner	Beneficial Ownership	
	Shares	Percentage

Steel Partners II, L.P. and affiliated entities (1) 590 Madison Avenue, 32nd Floor New York, New York 10022	2,433,297	14.9%
JANA Partners LLC (2) 536 Pacific Avenue San Francisco, California 94133	1,327,698	8.1%
Trellus Management Company, LLC (3) 350 Madison Avenue, 9th Floor New York, New York 10017	838,429	5.1%

The following table sets forth information as of March 1, 2005 with respect to the ownership of shares of our Common Stock by each person believed by management to be the beneficial owner of more than five percent of the outstanding Common Stock. The information is based on the most recent Schedule 13D or 13G filed with the SEC on behalf of such persons or other information made available to us.

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(1) Information obtained from Schedule 13D/A filed with the SEC by Steel Partners II, L.P. (Steel Partners) and Steel Partners, L.L.C. (SP LLC) on November 11, 2004. The Schedule 13D/A discloses that Steel Partners has sole power to vote or direct the vote of and to dispose of or to direct the disposition of all these shares. As the sole executive officer and managing member of SP LLC, Warren G. Lichtenstein may be deemed to beneficially own all of these shares.

(2) Information obtained from Schedule 13G/A filed with the SEC by JANA Partners LLC (JANA) on October 27, 2004. The Schedule 13G discloses that JANA Partners has sole power to vote or direct the vote of and to dispose of or to direct the disposition of all these shares.

(3) Information obtained from Schedule 13G/A filed with the SEC by Trellus Company, LLC (Trellus) and Adam Usdan on February 7, 2005. The Schedule 13G/A discloses that Trellus and Mr. Usdan have shared power to vote or direct the vote of and to dispose of or to direct the disposition of all these shares.

SECURITY OWNERSHIP OF MANAGEMENT

The following table sets forth information as of March 1, 2005 with respect to the beneficial ownership of our Common Stock by (1) each director and nominee for election as director, (2) each executive officer named in the Summary Compensation Table under Executive Compensation in this Proxy Statement and (3) all executive officers and directors as a group:

Name	Shares	Options	Beneficial Ownership	Percentage (1)
Thomas D. Weldon (2) (3) (4)	178,770	131,000	309,770	1.9%
Charles E. Larsen	311,161	29,000	340,161	2.1%
Alfred J. Novak	0	394,350	394,350	2.4%
J. Stephen Holmes	0	29,000	29,000	0.2%
William E. Whitmer	9,000	34,000	43,000	0.3%
Judy Lindstrom	0	25,250	25,250	0.2%
Stephen I. Shapiro	4,213	29,000	33,213	0.2%
Robert N. Wood, Jr.	1,018	107,788	108,806	0.7%
Daniel G. Hall	3,000	95,444	98,444	0.6%
Adam Lowe	0	129,132	129,132	0.8%
Andrew Green	228	66,950	67,178	0.4%
All executive officers and directors as a group (13) persons	507,390	1,199,783	1,737,173	15.2%

(1) Applicable percentage of ownership as of March 1, 2005 is based upon 16,334,705 shares of our Common Stock outstanding. A person is deemed to be the beneficial owner of our Common Stock that can be acquired within 60 days from March 1, 2005 upon the exercise of options, and that person s options are assumed to have been exercised (and the underlying shares of our Common Stock outstanding) in determining such person s percentage ownership. Consequently, the denominator for calculating such percentage may differ for each shareholder.

(2) Includes 2,500 shares held in trust for the benefit of Mr. Weldon s son and 2,500 shares held by Mr. Weldon as custodian for his nephew.

(3) Includes 39,668 shares held by Mr. Weldon s spouse.

(4) Includes 67,571 shares held by The Weldon Foundation, Inc., a Florida not-for-profit corporation in which Thomas D. Weldon is a director. Mr. Weldon disclaims beneficial ownership of all shares held by The Weldon Foundation, Inc.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Novoste has adopted a policy that all transactions between Novoste and its officers, directors, principal shareholders and their affiliates will be on terms no less favorable to Novoste than could be obtained by it from unrelated third parties, and will be approved by its Audit Committee.

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ITEM 14. PRINCIPAL ACCOUNTING FEES & SERVICES

Fees for the work performed by Ernst & Young LLP, an independent registered public accounting firm that audited our financial statements included in this Annual Report on Form 10-K, during 2004 and 2003, are set forth below:

(a) *Audit Fees*

Fees for audit services totaled approximately $920,000 in 2004 and approximately $502,000 in 2003, including fees associated with the annual audit, the audit of internal control over financial reporting, the reviews of the Company s Quarterly Reports on Form 10-Q, and statutory audits required internationally.

(b) *Audit-Related Fees*

Fees for audit-related services totaled approximately $0 in 2004 and approximately $40,000 in 2003. Audit-related services principally include accounting consultations concerning financial accounting and reporting matters not classified as audit fees.

(c) *Tax Fees*

Fees for tax services, including tax compliance, tax advice and tax planning totaled approximately $181,000 in 2004 and $217,000 in 2003.

(d) *All Other Fees*

Fees for all other services not included above totaled approximately $0 in 2004 and $68,000 in 2003, principally including support and advisory service relating to the corporate restructuring of European legal entities.

The Audit Committee approves, in advance, the provision by Ernst & Young of all services whether or not related to the audit. Applicable law and regulations provide an exemption that permits certain services to be provided by our outside auditors even if they are not pre-approved. We have not relied on this exemption at any time since the Sarbanes-Oxley Act was enacted. The Audit Committee typically meets with Ernst & Young throughout the year. The Audit Committee reviews both audit and non-audit services performed by Ernst & Young as well as fees charged by Ernst & Young for such services. In engaging Ernst & Young for the services described above, the Audit Committee considered whether the provision of such services is compatible with maintaining Ernst & Young s independence.

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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:

	Page Number
Report of Independent Registered Public Accounting Firm on Financial Statements	44
Report of Independent Registered Public Accounting Firm on Internal Control	45
Consolidated Balance Sheets as of December 31, 2004 and 2003	46
Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002	47
Consolidated Statements of Shareholders Equity for the years ended December 31, 2004, 2003 and 2002	48
Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002	51
Notes to Consolidated Financial Statements	52

2. *Financial Statement Schedules*

The following schedule is filed herewith:

Schedule II Valuation and Qualifying Account and Reserves	72

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.

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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 16, 2005.

NOVOSTE CORPORATION

By: /s/ ALFRED J. NOVAK

Alfred J. Novak

President and 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 16, 2005.

Signatures	Titles
/s/ ALFRED J. NOVAK **Alfred J. Novak**	President and Chief Executive Officer and Director (Principal Executive Officer)
/s/ SUBHASH C. SARDA **Subhash C. Sarda**	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ THOMAS D. WELDON **Thomas D. Weldon**	Chairman of the Board of Directors
/s/ J. STEPHEN HOLMES **J. Stephen Holmes**	Director
/s/ CHARLES E. LARSEN **Charles E. Larsen**	Director

/s/ JUDY LINDSTROM	Director
Judy Lindstrom	
/s/ STEPHEN I. SHAPIRO	Director
Stephen I. Shapiro	
/s/ WILLIAM E. WHITMER	Director
William E. Whitmer	

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Report of Independent Registered Public Accounting Firm on Financial Statements

The Board of Directors and Shareholders

Novoste Corporation

We have audited the accompanying consolidated balance sheets of Novoste Corporation (and subsidiaries) as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in the index at Item 15. These 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 the standards of the Public Company Accounting Oversight Board (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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Novoste Corporation (and subsidiaries) at December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with U. S. generally accepted accounting principles. 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Novoste Corporation s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2005, expressed an unqualified opinion thereon.

Ernst & Young LLP

Atlanta, Georgia

March 14, 2005

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Report of Independent Registered Public Accounting Firm

on Internal Control

The Board of Directors and Shareholders

Novoste Corporation

We have audited management s assessment, included in the accompanying Management s Report on Internal Control Over Financial Reporting, that Novoste Corporation maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Novoste Corporation s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that Novoste Corporation maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Novoste Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Novoste Corporation (and subsidiaries) as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2004 and our report dated March 14, 2005, expressed an unqualified opinion thereon.

Ernst & Young LLP

Atlanta, Georgia

March 14, 2005

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NOVOSTE CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except number of shares data)

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,082	$ 33,177
Short-term investments	9,978	6,225
Accounts receivable, net of allowance for doubtful accounts of $125 and $442, respectively	1,928	5,206
Inventory, net	1,206	2,439
Prepaid expenses and other current assets	807	480
Total current assets	33,001	47,527
Property and equipment, net	700	6,997
Radiation and transfer devices, net		6,304
Other assets	1	579
Total assets	$ 33,702	$ 61,407
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,511	$ 1,492
Accrued expenses	3,823	6,483
Unearned revenue	1,914	188
Total current liabilities	7,248	8,163
Shareholders equity:		
Preferred stock, $.01 par value, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, $.01 par value, 25,000,000 shares authorized; 16,377,634 and 16,371,997 shares issued, respectively	164	164
Additional paid-in capital	187,894	187,880
Accumulated other comprehensive income	826	733
Accumulated deficit	(162,223)	(135,302)
Treasury stock, at cost, 42,929 shares	(172)	(172)
Unearned compensation	(35)	(59)
Total shareholders equity	26,454	53,244
Total liabilities and shareholders equity	$ 33,702	$ 61,407

See accompanying notes.

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NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per-share data)

	Year Ended December 31,		
	2004	**2003**	**2002**
Net sales	$ 23,268	$ 62,901	$ 69,030
Cost of sales	16,111	24,315	27,313
Impairment charge	7,630		6,900
Gross margin	(473)	38,586	34,817
Operating expenses:			
Research and development	4,633	11,986	13,300
Sales and marketing	12,558	19,485	26,875
General and administrative	8,036	8,237	8,335
Impairment charge	1,719		
Total operating expenses	26,946	39,708	48,510
Loss from operations	(27,419)	(1,122)	(13,693)
Interest income	386	317	747
Interest expense	(3)	(32)	(105)
Other income (expense)	115	(31)	
Total other income	498	254	642
Net loss	$ (26,921)	$ (868)	$ (13,051)
Net loss per share basic and diluted	$ (1.65)	$ (0.05)	$ (0.80)
Weighted average shares outstanding basic and diluted	16,333	16,313	16,268

See accompanying notes.

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NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands, except per share amounts)

	Common Stock					Treasury Stock			
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Shares	Amount	Unearned Compensation	Total
Balance at January 1, 2002	16,265	$ 163	$ 187,357	$ (408)	$ (121,383)	(6)	$ (24)	$ (977)	$ 64,728
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 shares at $4.08 and 21 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)
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.

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NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands, except per share amounts)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated	Treasury Stock		Unearned	
	Shares	Amount	Capital	(Loss)	Deficit	Shares	Amount	Compensation	Total
Exercise of stock options at $3.20 to $6.65	4	$	$ 292	$	$	101	$ 382	$	$ 674
Issuance of stock under Employee Stock Purchase Plan, 19 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
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.

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NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands, except per share amounts)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated	Treasury Stock		Unearned	
	Shares	Amount	Capital	(Loss)	Deficit	Shares	Amount	Compensation	Total
Exercise of stock options at $3.70 per share	2	$	$ 7	$	$		$	$	$ 7
Issuance of stock under Employee Stock Purchase Plan, 4 shares at $2.2185	4		8						8
Amortization of unearned compensation								42	42
Revaluation of Variable Stock Awards			(6)					2	(4)
Compensation expense relating to fair market value of stock options to non employees			32					(27)	5
Cancellation of options for services or compensation			(27)					7	(20)
Comprehensive income (loss):									
Unrealized loss				(2)					(2)
Translation Adjustment				95					95
Net loss					(26,921)				(26,921)
Total Comprehensive loss									(26,828)
Balance at December 31, 2004	16,378	$ 164	$ 187,894	$ 826	$ (162,223)	(43)	$ (172)	$ (35)	$ 26,454

See accompanying notes.

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NOVOSTE CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2004	**2003**	**2002**
Cash flows from operating activities:			
Net loss	$ (26,921)	$ (868)	$ (13,051)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization of property, equipment and intangibles	3,706	3,295	3,125
Stock based compensation expense	23	145	470
Depreciation of radiation and transfer devices	4,124	8,606	9,241
Impairment charge	9,349		5,065
Provision for doubtful accounts	(191)	(410)	288
Changes in assets and liabilities:			
Accounts receivable	3,502	2,043	9,326
Inventory	1,091	1,521	(85)
Prepaid expenses and other current assets	(290)	508	36
Other assets	742	890	(285)
Accounts payable	(33)	(753)	(2,033)
Accrued expenses	(3,125)	(3,527)	(1,001)
Unearned revenue	1,723	(2,258)	(387)
Net cash (used in) provided by operating activities	(6,300)	9,192	10,709
Cash flows from investing activities:			
Maturity/sale of short-term investments	10,715	16,686	35,573
Purchase of short-term investments	(14,468)	(11,264)	(15,536)
Purchase of property and equipment, net	(517)	(723)	(2,730)
Purchase of intangibles	(2,500)		
Purchase of radiation and transfer devices	(1,106)	(3,557)	(12,124)
Net cash (used in) provided by investing activities	(7,876)	1,142	5,183
Cash flows from financing activities:			
Proceeds from issuance of common stock	15	768	636
Purchase of treasury stock		(109)	(616)
Repayment of capital lease obligations		(183)	(270)
Net cash provided by financing activities	15	476	(250)
Effect of exchange rate changes on cash	66	439	408
Net (decrease) increase in cash and cash equivalents	(14,095)	11,249	16,050
Cash and equivalents at beginning of year	33,177	21,928	5,878
Cash and cash equivalents at end of year	$ 19,082	$ 33,177	$ 21,928
Supplemental disclosure of cash flow information:			

Cash paid for interest	$	$ 15	$ 106

See accompanying notes.

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. SIGNIFICANT ACCOUNTING POLICIES

Organization and Basis of Presentation

Novoste Corporation (Novoste or 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 has been commercializing the Beta-Cath System, an intraluminal beta radiation catheter delivery system designed to reduce restenosis subsequent to percutaneous transluminal coronary angioplasty.

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 5F catheters that were sold to customers in 2002, which were subsequently exchanged when the new, redesigned 3.5F diameter catheters were relaunched in January 2003. This revenue was recognized during 2003 as these exchanges occurred. Selling expenses of $200,000 relating to this revenue reserve were deferred and were released as revenue was recognized. Cost of goods sold relating to this revenue reserve were deemed immaterial and therefore not deferred.

On February 22, 2005, Novoste announced a staged wind-down of operations (see Note 20). The accompanying financial statements are presented on a going-concern basis through December 31, 2004.

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.

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 distributor s 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 by mutual negotiation and settlement.

Sales of stents and catheters are final and revenue is recorded at time of shipment. Product is not returnable other than for shipping errors or warranty claims and these estimated amounts are reserved for, based on historical experience. In connection with the recall of 3.5F catheters in late 2002 and subsequent relaunch in early 2003 the Company offered to exchange defective 3.5F catheters for 5.0F catheters until the redesigned 3.5F catheters were available, and agreed to take back any unused 5.0F catheters for redesigned 3.5F catheters upon relaunch of the new 3.5F catheters. At December 31, 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. Selling expenses of $200,000 relating to this revenue reserve were deferred, and were released as revenue was recognized in 2003. The cost of goods sold relating to this revenue reserve were deemed immaterial and therefore not deferred.

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 after 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.

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 2004, 2003, and 2002, approximately $2,133,000, $1,239,000, and $4,547,000 respectively, of net sales related to the lease of radiation transfer devices were recorded.

Accounts Receivable

Accounts receivable at December 31, 2004 and 2003 include receivables due from product sales and amounts due under lease and service arrangements to hospitals relating to radiation and transfer devices. The Company performs periodic credit evaluations of its customer s financial condition and does not require collateral. Allowances for uncollectible accounts receivable represent estimates of expected credit losses based on periodic reviews of customer accounts and historical collection experience. The carrying amounts reported in the consolidated balance sheets for accounts receivable approximate their fair value.

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Advertising Costs

All advertising costs are expensed as incurred. Approximately $235,000, $547,000, and $838,000, were charged to advertising expense for the years ended December 31, 2004, 2003 and 2002, 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 3,285,000, 3,094,000 and 3,590,000 related primarily to stock options are not included in the per share calculations for 2004, 2003 and 2002, respectively, because all such securities are antidilutive for all years presented.

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 16.7%, 7.9%, and 6.2% of total revenues for the years ended December 31, 2004, 2003 and 2002, respectively. The Company experienced an immaterial amount of transaction gains and losses in 2004, 2003 and 2002 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 2004, 2003 and 2002 are reflected in Other Comprehensive Income (Loss) on the Consolidated Statements of Shareholders Equity. During 2004, the Euro appreciated against the dollar approximately 9%, resulting in approximately $95,000 of Other Comprehensive Income.

Inventories

Inventories are stated at the lower of cost or market on a first-in, first-out (FIFO) basis net of reserves for obsolete and slow moving inventory.

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Long Lived Assets and Impairment Analysis

In accordance with Statement of Financial Accounting Standards SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets are reviewed for impairment whenever events indicate that their carrying amount may not be recoverable. In such reviews, estimated 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. Due to the continuing decline in the Company s current and projected future revenues and cash flows, during 2004, the Company evaluated the recovery of its long-lived assets and recorded an impairment charge of $9,349,000 on long-lived assets, including property and equipment, radiation and transfer devices, and other assets (see Note 15).

Property and Equipment

Property and equipment, including amounts under capital leases, if any, 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. During 2004, the Company recorded an impairment charge of $9,349,000, of which $4,187,000 related to property and equipment. (see Note 15).

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.

The Beta-Cath system consists of two major components: RSTs which provide the Beta radiation for patient treatment, and TD s which provide the mechanism for control of the RST during a VBT procedure and stores the RST between uses. Prior to entering commercial usage, the lives are based on experimental testing. Once in commercial service, data from the field is utilized to update the estimated lives. Thus, the useful economic life may change over time, based on new information.

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 of that product 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

contractual commitments were recognized in the second quarter for the estimated fair value of the 5.0F diameter system (Note 15). Depreciation on the remaining fair value of the 5.0F assets (after the impairment charge) had been accelerated and 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 (see Note 15).

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 (RSTs) and 36 months (TDs)	$ (3,838)
Impairment of $5,065 and other related charges of $1,800 on 30mm and 40mm 5.0F RSTs and TDs (Note 15)	6,865
Acceleration of useful lives of 60mm 5.0F RSTs and TDs	612
Net impact	$ 3,639
Net effect on loss per share	$ (0.22)

The impact on cost of sales for 2003 was immaterial and there is zero impact for 2004.

During 2004, the Company recorded a total impairment charge of $9,349,000 of which $3,443,000 related to radiation and transfer devices (see Note 15).

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* or (SFAS 123) sets forth accounting and reporting standards for stock-based employee compensation plans (see 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*.

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In December 2002, the Financial Accounting Standards Board issued SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure.* 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 2004, 2003 and 2002: 5-year treasury bill interest rates of 1.95%, 4.22% and 4.24%, respectively; no dividend yields; volatility factor of the expected market price of the Company s common stock of 0.68, 0.80 and 1.24, in 2004, 2003 and 2002, respectively; and a weighted-average expected life of the option of five years for 2004, 2003 and 2002.

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,		
	2004	2003	2002
Net loss, as reported	$ (26,921)	$ (868)	$ (13,051)
Add: Total stock-based employee compensation expense included in net loss	23	145	470
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(2,218)	(3,914)	(7,006)
Pro forma net loss	$ (29,116)	$ (4,637)	$ (19,587)

Loss per share:			
Basic and diluted as reported	$ (1.65)	$ (0.05)	$ (0.80)
Basic and diluted pro forma	$ (1.78)	$ (0.28)	$ (1.20)
Weighted average shares outstanding basic and diluted	16,333	16,313	16,268

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In December 2004, the FASB issued FASB Statement No. 123(R), *Share Based Payment* (SFAS 123(R)). SFAS 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. SFAS 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. The revised Statement generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB 25, which was permitted under SFAS 123, as originally issued. The revised Statement requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements. SFAS 123(R) is effective for the Company after June 15, 2005 (i.e., for our third quarter 2005). All public companies must use either the modified prospective or the modified retrospective transition method. We are currently evaluating the impact of adoption of this pronouncement, which must be adopted in the third quarter of fiscal year 2005.

Reclassifications

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

2. SHORT-TERM INVESTMENTS

At December 31, 2004 and 2003, 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, 2004 were as follows (in thousands):

	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Loss	Estimated Fair Value
Money market	$ 12,650	$	$	$ 12,650
Commercial paper	6,171		(1)	6,170
Asset backed bonds	502		(1)	501
Corporate bonds	3,919		(3)	3,916

Government bonds	3,307		(3)	3,304
Total available-for-sale investments	26,549	$	$ (8)	$ 26,541
Less amounts classified as cash equivalents	(16,563)			
Unrecognized net loss	(8)			
	$ 9,978			

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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			

The amortized cost and estimated fair value of available-for-sale investments in debt securities and other investments at December 31, 2004, by contractual maturity, were as follows (in thousands):

	Adjusted Cost	Estimated Fair Value
Due in 1 year or less	$ 25,426	$ 25,423
Due in 1-2 years	620	617
Due in 2-5 years	503	501
Total investments in available-for-sale securities	$ 26,549	$ 26,541

3. ACCOUNTS RECEIVABLE

Accounts receivable include amounts due from customers for product sales and amounts due under lease and maintenance or service agreements with hospitals relating to radiation and transfer devices (see Note 6). The carrying amounts approximate their fair value.

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

	December 31, 2004	December 31, 2003
Accounts receivable, gross	$ 2,053	$ 5,648
Less: Allowance for doubtful accounts	(125)	(442)
Accounts receivable, net	$ 1,928	$ 5,206

There were no significant concentrations of credit risk in 2004 or 2003.

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. INVENTORIES

Inventories are comprised of the following (in thousands):

	December 31, 2004	December 31, 2003
Raw materials	$ 1,922	$ 2,442
Work in process	133	124
Finished goods	871	1,115
Inventory, gross	2,926	3,681
Less: inventory reserve	(1,720)	(1,242)
Inventory, net	$ 1,206	$ 2,439

Inventory reserves increased from $1,242,000 at December 31, 2003 to $1,720,000 at December 31, 2004. The increase is attributable to additional reserves for excess inventory based on continuing declines in estimated future sales.

5. PROPERTY AND EQUIPMENT

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

	December 31, 2004	December 31, 2003
Furniture and fixtures	$ 791	$ 1,211
Office equipment	1,979	4,142
Laboratory equipment	552	991
Leasehold improvements	543	2,208
Production equipment	5,092	8,205

Property and equipment, gross	8,957	16,757
Less: Accumulated depreciation and amortization	(8,257)	(9,760)
Property and equipment, net	$ 700	$ 6,997

Depreciation expense on property and equipment was $2,603,000, $3,280,000 and $3,021,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

During 2004, the Company recorded an impairment charge of $9,349,000, of which $4,187,000 related to property and equipment (see Note 15).

Novoste is obligated to decommission the radiation production facility at the conclusion of operations when the plant is retired. Novoste receives, from time to time, estimates of the cost of the decommissioning activity. These costs are accounted for in accordance with SFAS 143, *Accounting for Asset Retirement Obligations.* At December 31, 2004, based on the latest estimates, Novoste had recorded a liability of $621,000 and corresponding net asset of $233,000, an increase from $101,000 and $68,000 respectively, recorded at the end of 2003. The increase is due to a change in the estimated costs to be incurred through the third quarter of 2006 when the plant will be retired, approximately $469,000, and to an increase in the EUR/USD exchange rate during the year, approximately $51,000. The corresponding increase in net asset balance was $165,000. No liabilities were settled during 2003 or 2004 and no payments are expected to be made until the retirement is complete.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. RADIATION AND TRANSFER DEVICES

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

	December 31, 2004	December 31, 2003
Radiation and transfer devices, gross	$ 14,977	$ 25,554
Less: Accumulated depreciation	(14,977)	(19,250)
Radiation and transfer devices, net	$	$ 6,304

During 2002, an impairment charge of $5,065,000 was recognized in the second quarter for 5.0F radiation devices. During 2004, the Company recorded an impairment charge of $9,349,000, of which $3,443,000 related to radiation and transfer devices (see Note 15).

7. OTHER ASSETS

Other assets consist mainly of license agreements and other intangibles. On April 22, 2004, Novoste signed an asset purchase agreement with Guidant Corporation (Guidant) pursuant to which Novoste acquired information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant in the United States and Canada. Under the terms of the agreement, during a six-month transition period, which began on April 22, 2004, Guidant and Novoste agreed to cooperate jointly to transition the Guidant customers to Novoste products for any customer that wished to continue vascular brachytherapy. Guidant agreed to discontinue its vascular brachytherapy business in the United States and Canada over the six-month period. Additionally, Guidant agreed to not compete in the vascular brachytherapy market in the United States and Canada for a period of five years. Novoste paid the sum of $2,500,000 to Guidant at the signing of the transaction for the Guidant customer list. In addition, the Company agreed to pay Guidant an additional 5% on net sales to customers on the Guidant customer list that transition to Novoste s products, for a period of six months after April 22, 2004. After the six-month transition period, Novoste agreed to pay an additional 5% on all U.S. and Canadian net sales of Novoste vascular brachytherapy products up to a maximum of $4,000,000. The initial payment was being amortized over twenty-four months. Amortization expense was $833,000 for the twelve months ended December 31, 2004.

During 2004, the Company recorded an impairment charge of $9,439,000, of which $1,719,000 related to other assets consisting of licenses, patents and the Guidant customer list (see Note 15).

8. ACCRUED EXPENSES

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

	December 31, 2004	December 31, 2003
Salaries, wages and benefits	$ 1,216	$ 2,353
Accrued supplier and radiation decommissioning cost	891	1,598
Due to customers	104	310
Operating expenses and royalties	433	643
Clinical trials	205	783
Professional fees	892	584
Sales and use taxes	82	212
	$ 3,823	$ 6,483

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. LINE OF CREDIT

In August 2001, the Company obtained a $10 million revolving line of credit, which was extended by agreement from time to time. At December 31, 2003 the Company had no outstanding borrowings against the line of credit. On May 27, 2004, Novoste replaced previous borrowing arrangements with a one-year agreement, which provided a $5,000,000 revolving line of credit and the availability of letters of credit. On December 22, 2004, in view of declining business needs, Novoste terminated the borrowing agreement with the financial institution and no obligations related to the agreement exist at December 31, 2004. At December 31, 2004, the Company had $75,000 in outstanding letters of credit.

10. CAPITAL LEASE OBLIGATIONS

The Company leased computers and equipment under capital leases with initial or remaining terms in excess of one year or more. During 2003, all obligations under capital leases were satisfied and no future lease obligations existed at December 31, 2003 and 2004.

For the year ended December 31, 2003, lease payments under capital leases were $183,000. Depreciation expense associated with capital leases was $150,000 and $262,000 for 2003 and 2002, respectively. These amounts were included in operating expenses.

11. 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, 2004	December 31, 2003
Deferred income tax assets:		
Net operating loss carryforwards	$ 30,086	$ 52,594
R&D tax credit carryforwards	3,143	2,920
Provision for doubtful accounts	10	57
Other	3	3
Accruals/reserves	5,156	3,034

Property and equipment	1,281	1,142
	39,679	59,750
Valuation allowance for deferred income tax assets	(39,679)	(59,750)
Net deferred income tax assets	$	$

At December 31, 2004 and 2003, 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 2004, 2003, or 2002. As of December 31, 2004, the Company has approximately $63,019,000 of net operating loss carryforwards (NOL carryforwards) for U.S. federal income tax purposes remaining after certain limitations pursuant to Section 382 of the Internal Revenue Code (IRC) imposed during 2004 (see discussion below). Such losses expire in 2007 through 2024. As of December 31, 2004, the Company has approximately $14,323,000 of foreign net operating losses related to its European subsidiaries. Additionally, the Company has approximately $3,142,000 in research and development (R&D) tax credits that expire in 2008 through 2024 unless utilized earlier. However, because of the IRC Section 382 limitation (see discussion below), all but approximately $223,000 of R&D tax credits will likely expire

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

unused. The NOL carryforwards 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 in the Act.

The Company had previously reported in the audited consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2003, that it had approximately $108,000,000 of NOL carryforwards which were fully reserved and will expire beginning 2007 through 2023. Section 382 of the Internal Revenue Code (IRC) imposes an annual limitation on the utilization of NOL carryforwards based on a statutory rate of return (the adjusted Federal long term rate , as defined in the IRC) and the value of the corporation at the time of a change in ownership as defined by Section 382 of the IRC. As a result the Company evaluates whether there are limitation on the use of its NOL carryforwards, including the impact of cumulative changes in ownership of the Company s common stock. This evaluation includes reliance upon the filings of Schedules 13D and 13G by certain stockholders in accordance with Securities and Exchange Commission (SEC) rules as well as additional reviews by the Company.

In connection with its review of a potential strategic alternative during the fourth quarter of 2004, the Company completed a review of whether there were limitations on the use of its NOL carryforwards. During the foregoing review, the Company became aware of what it believed were potential inaccuracies contained in certain Schedule 13D and 13G filings made by certain persons with the SEC during the past several years and has determined that certain purchases and sales of its common stock were not reported accurately. As a result, the Company determined that a change in ownership, as defined in Section 382 of the IRC, took place on September 17, 2003, which imposes annual limitations restricting the timing and amounts of the future use of available NOL carryforwards. As a consequence of these limitations, approximately two-thirds of the NOL carryforwards will expire unused.

As of September 17, 2003, the future use of NOL carryforwards is limited to $1.8 million annually. All of the NOL carryforwards are fully reserved and will expired over a 17-year period beginning in 2007. The change in ownership had no impact on reported net income or loss per share for the years ended December 31, 2004 or 2003.

The utilization of these NOL carryforwards could be further restricted in future periods as a result of any future changes in ownership, as defined in Section 382 of the IRC. Such future change in ownership, if any, may result in significant additional amounts of these NOL carryforwards expiring unused.

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

	2004	2003	2002
Tax benefit at statutory rate	$ (9,396)	$ (295)	$ (4,437)

State tax, net of federal benefit	(1,073)	(23)	(482)
R&D tax credit	(223)	(571)	(925)
Other	34	101	346
Valuation allowance for deferred income tax	10,658	788	5,498
	$	$	$

12. 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

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 $^{1}/_{100^{th}}$ (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 immediate 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 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 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 immediate 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. During 2004, the 2001 Plan was amended to make an additional 500,000 shares available for grant. Under the 2001 Plan, 875,200 shares were granted and 391,665 shares were canceled in 2004, and 134,800 shares remain available for grant as of December 31, 2004.

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Plan, 12,000 shares were granted, 2,000 shares were exercised and 69,512 shares were canceled in 2004, and 80,662 shares remain available for grant as of December 31, 2004.

Effective October 16, 2002, the Board of Directors adopted the Novoste Corporation 2002 Chief Executive Officer Stock Option Plan which authorizes the grant of 700,000 shares to the Company s Chief Executive Officer. All of the shares authorized were granted to Alfred J. Novak on October 16, 2002, as non-qualified stock options, at an exercise price of $4.20 per share, the fair market price of the stock on the date of the grant. The options are exercisable at various times during the term of the grant, which is a period of ten years. No shares remain available for grant under this Plan.

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

	Number of Shares	Price per Share		Weighted Average Price
Outstanding at December 31, 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
Options granted	887,200	1.49	5.20	2.99
Options exercised	(2,000)	3.70	3.70	3.70
Options forfeited	(693,460)	2.90	49.25	11.63
Outstanding at December 31, 2004	3,285,304	1.49	49.25	7.38
Exercisable at December 31, 2004	1,732,555	3.20	49.25	10.54

At December 31, 2004 the Company has 3,500,766 shares of common stock reserved for issuances under these employee and director stock option arrangements and 124,727 shares of common stock reserved for issue under the Employee Stock Purchase Plan (see Note 14).

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	1,882,463	8.64	$ 3.64	499,550	$ 4.21
5.01	7.00	718,102	7.19	6.47	615,160	6.55
7.01	10.50	130,750	7.79	7.86	72,614	7.78
10.51	13.38	157,912	4.11	11.53	157,912	11.53
13.39	21.94	71,400	6.43	15.28	63,928	15.19
21.95	22.50	97,452	5.80	22.50	97,452	22.50
22.51	24.69	108,200	3.42	24.00	108,150	24.00
24.70	49.25	119,025	3.79	33.76	117,789	33.79
		3,285,304	7.59	7.38	1,732,555	10.54

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 expense of $1,793,000, which has been expensed over the four-year vesting period of these options: $0, $0 and $127,000 have been expensed in 2004, 2003 and 2002, 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 expense of $839,000, which has been 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 $14,000, $114,000 and $210,000 were expensed in 2004, 2003 and 2002, 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 grants of any options for at least six months after the date of the surrender of the options.

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 is 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 2004 is $1.72.

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, 2004, the remaining 46,475 restricted shares have vested, have been recorded as unearned compensation in the statement of shareholders equity and were amortized to compensation expense over the vesting periods of the awards. Holders of these shares have voting rights after the shares vest. Based on the quoted market value per share at the grant dates, the Company incurred compensation expense of $3,000, $25,000 and $55,000 in 2004, 2003 and 2002, respectively.

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, the purchases could 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

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2003, the Company announced the extension of the stock buy-back program originally authorized in 2002 for an additional one year period and increased the authorized expenditure for stock repurchase up to $7 million. No repurchases occurred during 2004 and the program has expired. As of December 31, 2004, 185,400 shares have been purchased for $725,000 under the buy-back program.

13. COMMITMENTS AND CONCENTRATIONS OF SUPPLIERS

The Company is committed under operating leases for its facility and various equipment. Rent expense was approximately $752,000, $827,000, and $770,000 for the years ending December 31, 2004, 2003 and 2002, respectively. The total future minimum rental payments at December 31, 2004 are as follows (in thousands):

2005	$ 369
2006	45
	$ 414

On January 3, 1996, the Company 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), up to a maximum payment of $5,000,000. Royalty fees to the physician aggregated, $206,000 $585,000, and $668,000 in 2004, 2003 and 2002 and have been expensed in cost of sales.

On January 30, 1996, the Company entered into a license agreement whereby Emory University assigned its claim to certain technology to the Company for royalties based on net sales (as defined in the agreement) of products derived from such technology, subject to certain minimum royalties. After the first commercial sale of royalty bearing products by Novoste, minimum royalties were due to Emory University in the following amounts: year 2 after the first commercial sale $10,000; year 3 $15,000; year 4 $25,000; and years 5-10, $50,000 per year. The royalty agreement term is consistent with the life of the related patent and applies to the assignments of the patent technology to a third party. Royalty fees to Emory University aggregated $468,000, $1,192,000, and $1,378,000, in 2004, 2003 and 2002, respectively, and have been expensed in cost of sales.

On April 22, 2004, Novoste signed an asset purchase agreement with Guidant pursuant to which Novoste would acquire information regarding Guidant s vascular brachytherapy business, including the customer list of Guidant in the United States and Canada. Novoste paid the sum of $2,500,000 to Guidant at the signing of the transaction and agreed to pay 5% on its net sales to customers on the Guidant customer list that transition to Novoste s products for a period of six months after April 22, 2004. After this six month transition period, Novoste will pay an additional 5% on all vascular brachytherapy products in the U.S. and Canada, up to an additional payment of $4,000,000. Under this agreement, Guidant has earned $227,000 in additional payments during 2004 (see Note 7).

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 2006. Commitments under the contracts were $1,700,000 and $10,446,000 at December 31, 2004 and 2003, respectively. The contractual obligation under the AEA contract is subject to negotiation and settlement with AEA.

At December 31, 2004, the Company has disposal requirements for radioactive isotopes and contractual cost reimbursement obligations for decommissioning contaminated production equipment. The Company has accrued $250,000 for the 5.0F production equipment disposal and $19,000 for 5.0F isotope seed disposal, which are recorded in accrued expenses and are expected to be paid to Bebig during the first two quarters of 2005.

The Company is contractually obligated for decommissioning the radiation manufacturing facility when it is retired in the third quarter of 2006 (see Note 5). Novoste receives estimates from time to time regarding the cost of decommissioning and records the estimate as a liability. The estimate is provided in Euros, thus, the fair value

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of the liability in USD is calculated using the Euro/USD exchange rate at the balance sheet date and discounted using the risk-free interest. The total liability at December 31, 2004 is $659,000, which is discounted at 3.64% to determine the liability amount of $621,000 on the balance sheet. Payments will not occur until retirement of the facility in 2006. The estimate of the decommissioning cost is subject to revision as the Euro/USD exchange rate changes, as disposal methods and technologies change, and as possible alternate uses for the equipment develop between now and the retirement date in 2006.

The Company maintains termination agreements with certain executives providing for severance pay and other related benefits upon the executive s separation from the Company under a change of control. In addition, there are retention bonus agreements for certain executives which provide for continued loyalty to Novoste during the restructuring period.

The Company is subject to legal claims and assertions in the ordinary course of business. At December 31, 2004, 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 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.

14. 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 2004, 2003 and 2002 the Company matched 33 1/3% of the first 6% of employee contributions, aggregating $173,000, $199,000, and $293,000, 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, 2004, 124,727 shares have been purchased under the Plan.

15. IMPAIRMENT CHARGES

In 2002, impairment and related charges of $6,900,000 associated with the Company s U.S. operations were recorded 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

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

generated by the transfer devices and radiation source trains during their remaining service lives, discounted at the risk-free rate of interest. The remaining fair value was amortized ratably over the estimated useful life of these assets, which extended through December 31, 2003. At December 31, 2003, the net book value of all 5.0F assets was zero.

During the third quarter of 2004, Novoste suspended production of radiation source trains at AEA Technologies QSA GmbH (AEA). This suspension was due to the existence of sufficient radiation source train inventory levels that were determined to be adequate to meet the needs of Novoste for the foreseeable future. This situation was due to (a) the reduction in the number of vascular brachytherapy sites and procedures as a result of the declining vascular brachytherapy market, and (b) fewer replacements of 3.5F radiation source trains than expected. As a result of the suspension and continued declines in the Company s current and projected future revenues and cash flows, Novoste assessed the recoverability of carrying value of the Company s long-lived assets in relationship to the expected undiscounted cash flows to be generated from revenues. Based on this evaluation, Novoste concluded that the value of the AEA plant was no longer fully recoverable and recorded an impairment charge of $938,000, or $.06/share, against the carrying value of $2,865,000 in property and equipment in the plant. In addition, effective September 30, 2004, Novoste concluded that the estimated useful commercial life of the production facility should be reduced from 60 months to 48 months, ending September 2006 when the AEA Supply Agreement is up for renewal. The remaining value of the AEA plant was to be depreciated over this remaining useful life.

During the fourth quarter of 2004, the Company updated an economic study regarding the value of all long-lived assets supporting the VBT business. The impairment analysis was based on expected future net cash flows to be generated by the assets during their remaining service lives, using undiscounted cash flows. Because the Company only has one product line, all enterprise-wide, long-lived assets were included. The study concluded that the assets were impaired, and the carrying value of all long lived assets was reduced by $8,411,000, or $.51/share, and expensed as follows: in cost of sales, $6,692,000; in sales and marketing, $1,667,000; and in general and administrative, $52,000. Approximately $95,000 applied to long-lived assets in Europe. All of the specialized assets relating to the Beta-Cath product line were considered to have zero fair value due to their specialized nature and lack of alternative uses. Property and equipment, much of which is more versatile in nature, was reduced to estimated salvage value.

16. PERSONNEL TERMINATION COSTS

During the years ended December 31, 2004 and 2003, 84 and 87 employees, respectively, were terminated, to align the Company s staffing with current market conditions. All costs related, directly or indirectly, to the personnel affected were expensed (and paid) in year of employment termination. These costs are included in cost of sales and operating expense on the consolidated statement of operations for the years ended December 31, 2004 and 2003.

	Year Ended December 31,	
	2004	2003

Accrued from prior period, paid during current period	$	$
Accrued and paid during current period	676	565
Accrued but not paid during current period		
Termination expense for the period	$ 676	$ 565
Expense reported in:		
Cost of Sales	$ 274	$
Operating Expenses	$ 402	$ 565

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. 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 President and Chief Executive Officer, Mr. Alfred J. Novak, is also the Chairman of Orbus. During 2004, the Company purchased $119,000 of product from Orbus. As of December 31, 2004, and 2003 the Company has prepaid $60,000 and $169,000 for future product purchases and had $169,000 and $341,000 in inventory. In the years ending December 31, 2004 and 2003, Novoste had net sales of $430,000 and $620,000 from this product line.

Subsequent to December 31, 2004, Novoste and Orbus mutually agreed to terminate the Distribution Agreement. Orbus paid Novoste $366,000 and assumed $38,000 in liabilities to repurchase inventory, refund the unused deposit and reimburse Novoste for market development expenses. Novoste will cease distributing Orbus product by the end of the first quarter of 2005.

18. 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
2004	$ 19,391	$ 3,877	$ 23,268
2003	57,915	4,986	62,901
2002	64,746	4,284	69,030

Net income (loss)	United States	Rest of World	Consolidated
2004	$ (26,293)	$ (628)	$ (26,921)
2003	(932)	64	(868)
2002	(8,109)	(4,942)	(13,051)

Long-lived assets	United States	Rest of World	Consolidated
2004	$ 700	$	$ 700
2003	12,689	1,191	13,880

Total assets	United States	Rest of World	Consolidated
2004	$ 31,794	$ 1,908	$ 33,702
2003	57,264	4,143	61,407

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

	(In thousands, except per share amounts)			
Fiscal 2004	**First Quarter Ended March 31**	**Second Quarter Ended June 30**	**Third Quarter Ended September 30**	**Fourth Quarter Ended December 31**
Net sales	$ 7,025	$ 5,753	$ 5,952	$ 4,538
Cost of sales	3,952	3,539	4,350	4,270
Impairment charge			938	6,692
Gross margin	3,073	2,214	664	(6,424)
Loss from operations	(4,691)	(3,886)	(5,440)	(13,402)
Net loss	(4,614)	(3,770)	(5,273)	(13,264)
Net loss per share	(0.28)	(0.23)	(0.32)	(0.81)

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
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)

Cost of sales and gross margin for the first and second quarter of 2004 have been changed from the presentation in our 10-Q s in order to be consistent with the presentation made for the third and fourth quarters and for prior years. Administration and facilities costs in the amounts of $77,000 and $76,000 for the first and second quarter, respectively, are reclassified to cost of sales, which correspondingly reduced gross margin. The total results of operation does not change.

20. SUBSEQUENT EVENTS

On February 22, 2005, the Company announced that the board of directors had determined that the vascular brachytherapy products business, which is the Company s only business line is no longer viable, and as a result, the Board had authorized a staged wind-down of the VBT business. On that date, Novoste also announced that, pursuant to the first stage of the wind-down plan, it would reduce the U.S. workforce in the first quarter of 2005 by 52 employees, from 81 employees. Additionally, the Company notified all its employees outside of the U.S. (16) that they will be terminated in accordance with their contracts and the relevant country s employment regulations in an effort to further reduce the Company s costs. The board determined that this decision was necessary to preserve cash resources and arose as a result of the continuing decline in revenue for the Company s vascular brachytherapy products.

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NOVOSTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 2004				
Allowance for doubtful accounts	$ 442	$ (206)	$ (111)	$ 125
Inventory reserves	1,242	1,327	(849)	1,720
Returns and warranty reserve	10	2	(10)	2
Fiscal Year 2003				
Allowance for doubtful accounts	$ 1,135	$ (377)	$ (316)	$ 442
Inventory reserves	844	398		1,242
Returns and warranty reserve	81	4	(75)	10
Catheter exchange reserve	2,150		(2,150)	
Fiscal Year 2002				
Allowance for doubtful accounts	$ 878	$ 372	$ (115)	$ 1,135
Inventory reserves	15	829		844
Returns and warranty reserve		195	(114)	81
Catheter exchange reserve			2,150	2,150

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INDEX TO EXHIBITS

Exhibit Numbers	Description
3.1	Amended and Restated Articles of Incorporation of Registrant filed on May 28, 1996. (14)
3.2(a)	Copy of First Amendment to Amended and Restated Articles of Incorporation of Novoste Corporation filed with the Department of State of the State of Florida on November 1, 1996. (2)
3.3	Copy of Third Amended and Restated By-Laws of Registrant adopted May 5, 2003 (15)
3.4	4.1 Form of Specimen Common Stock Certificate of Registrant. (1)
4.17(a)	Amended and Restated Rights Agreement, dated as of July 29, 1999, between Novoste Corporation and American Stock Transfer & Trust Company, which includes as Exhibit B thereto the Form of Right Certificate. (2)
4.17(b)	Amended and Restated Summary of Rights to Purchase Preferred Shares of Novoste Corporation. (2)
4.20	Registration Rights Agreement dated as of March 28, 2000 by and among Novoste Corporation and the investors listed on the signature pages thereto. (11)
*10.1	Copy of Stock Option Plan of Registrant, as amended. (3)
H10.2	License Agreement, dated January 30, 1996, between Emory University and Registrant. (1)
H10.4	License Agreement, dated January 31, 1996, between Spencer B. King III, M.D. and Registrant. (1)
H10.5	Restenosis Therapy Project Development and Supply Agreement dated November 28, 1994, with Registrant, relating to the supply of radioactive beta isotopes. (1)
H10.6	Option to Purchase Assets Agreement dated August 22, 1995, with Registrant relating to the purchase of assets of Registrant s supplier of radioactive beta isotopes. (1)
H10.10	Frame Agreement with Bebig Isotopentechnik und Umweltdiagnostik GmbH regarding purchases and investment grant. (14)
*10.12	Copy of Non-Employee Director Stock Option Plan. (3)
H10.13	Memorandum of Understanding between Registrant and Bebig Isotopentechnik und Umweltdiagnostik GmbH regarding purchases and investment grant dated April 23, 1997. (4)*
10.14	Employment Agreement with William A. Hawkins III. (5)
*10.16	Restricted Stock Award Agreement with William A. Hawkins III. (5)
*10.17	Non-Incentive Stock Option Agreement with William A. Hawkins III. (5)
H10.18	Amendment to Framework Agreement and Security Agreement with Bebig GmbH, dated February 11, 2000 (5)
10.19	Lease, dated October 23, 1998, between Weeks Realty, L.P. and Registrant. (6)
H10.20	Manufacturing and Supply Agreement dated April 21, 1998 between Registrant and SeaMED Corporation. (7)
#10.20a	Manufacturing and Supply Agreement dated September 1, 1999 between Registrant and SeaMED, a Plexus Company. (10)
*10.22	Restricted Stock Award dated July 1, 1999 between Novoste Corporation and William A. Hawkins. (8)
H10.25	Development and Manufacturing Agreement between AEA Technology QSA GmbH and Novoste Corporation. (9)
H10.29	Amendment to the Framework Agreement and Security Agreement (NOV 34) between Registrant and Bebig Isotopentechnik und Umweltdiagnostik GmbH. (13)
10.30	Loan and Security Agreement dated August 1, 2001 between Silicon Valley Bank and Novoste Corporation. (12)

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Exhibit Numbers	Description
10.31	Negative Pledge Agreement dated August 1, 2001 between Silicon Valley Bank and Novoste Corporation. (12)
10.32	Form of change of control agreement executed between Novoste Corporation and Executive officers. (12)
10.34	Employment Agreement with Alfred Novak dated October 8, 2002. (14)
10.35	Non-Qualified Stock Option Agreement with Chief Executive Officer dated October 16, 2002. (14)
10.36	Non-Qualified Stock Option Agreement with Chief Executive Officer dated October 16, 2002. (14)
10.37	2002 Chief Executive Officer Stock Option Plan. (14)
*10.38	Form of amended and restated termination agreement for executive officers other than Alfred J. Novak. (17)
*10.39	Form of amended and restated termination agreement for Alfred J. Novak. (17)
*10.40	Novoste Corporation 2002 Broad-Based Stock Plan (16)
21	Subsidiaries of Novoste Corporation.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification of Alfred J. Novak, Chief Executive Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Subhash C. Sarda, Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Statements of Alfred J. Novak, Chief Executive Officer, and Subhash C. Sarda, Acting Chief Financial Officer, pursuant to 18 U.S.C. Section 1350.

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

(1) Filed as same numbered Exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-4988).
(2) Filed as same numbered Exhibit to the Registrant s Report on Form 8-A filed on November 5, 1996.
(3) Filed as Exhibit A to the Registrant s Proxy Statement for its 1999 Annual Meeting of Stockholders filed on April 12, 1999.
(4) Filed as same numbered Exhibit to the Registrant s Registration Statement on Form S-3 (File No. 333-38573).
(5) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed on August 11, 1998.
(6) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed on November 9, 1998.
(7) Filed as same numbered Exhibit to the Registrant s Report on Form 8-K filed on January 27, 1999.
(8) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed on August 11, 1999.
(9) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed on November 5, 1999.
(10) Filed as same numbered Exhibit to the Registrant s Report on Form 10-K filed February 18, 2000
(11) Filed as same numbered Exhibit to the Registrant s Report on Form 8-K filed April 6, 2000.
(12) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed November 14, 2001.
(13) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed August 14, 2001.
(14) Filed as same numbered Exhibit to the Registrant s Report on Form 10-K filed on March 31, 2003.
(15) Filed as same numbered Exhibit to the Registrant s Report on Form 10-Q filed on May 9, 2003.
(16) Filed as Exhibit 4.2 to the Registrant s Registration Statement on Form S-8 (File No. 333-108352).
(17) Filed as Exhibit 99.1 and 99.2, respectively, to the Registrant s Report on Form 8-K filed May 20, 2003.

* Constitutes a compensatory plan, contract or arrangement.