

NOVOSTE CORP /FL/  
Form DEFM14A  
August 04, 2005  
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## SCHEDULE 14A INFORMATION

### Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant

Filed by a Party other than the Registrant

Preliminary Proxy Statement

Confidential For Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

Definitive Proxy Statement

Soliciting Material Pursuant to Rule 14a-12

#### NOVOSTE CORPORATION

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(Name of Registrant as Specified In Its Charter)

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(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

No Fee required

Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

**Common stock and Series A preferred stock of ONI Medical Systems, Inc. ( ONI ) to be acquired by Novoste Corporation ( Novoste ) in exchange for shares of Novoste s common stock**

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(2) Aggregate number of securities to which transaction applies:

**5,929,806 shares of ONI s common stock, options and warrants to purchase 3,144,940 shares of ONI s common stock and 9,147,285 shares of ONI s Series A preferred stock to be acquired by Novoste in exchange for up to 32,951,560 shares of Novoste s common stock pursuant to the merger of a wholly owned subsidiary of Novoste with and into ONI**

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(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (Set forth the amount on which the filing fee is calculated and state how it was determined):

**one third of \$0.01, which is one third of the par value per share of each of the ONI common stock and the ONI Series A preferred stock**

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(4) Proposed maximum aggregate value of transaction: \$60,741

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(5) Total fee paid: \$8.00

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Fee paid previously with preliminary materials.

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

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(2) Form, Schedule or Registration Statement No. :

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(3) Filing Party:

(4) Date Filed:

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**Novoste Corporation**

**4350 International Boulevard**

**Norcross, Georgia 30093**

**(770) 717-0904**

**August 4, 2005**

**MERGER PROPOSED YOUR VOTE IS VERY IMPORTANT**

Dear Shareholder:

You are cordially invited to attend a special meeting of shareholders in lieu of an annual meeting to be held at 9:00 a.m., local time, on September 14, 2005 at the JW Marriott Hotel Buckhead Atlanta, 3300 Lenox Road, Atlanta, Georgia.

At the special meeting, among other things, you will be asked to approve (a) the issuance of shares of our common stock to the shareholders of ONI Medical Systems, Inc., a privately held Delaware corporation, pursuant to the terms of an agreement and plan of merger that we have entered into with ONI under which ONI will become our wholly owned subsidiary and (b) an amendment to our articles of incorporation to increase the authorized number of shares of our common stock from 25,000,000 to 75,000,000.

After careful consideration, our board of directors has unanimously (with one director recused from the matters) determined that the merger with ONI and the related merger agreement are advisable, fair to and in the best interests of our shareholders, has approved the merger agreement, the share issuance and the two amendments to our articles of incorporation described in the accompanying proxy statement, and has recommended that you vote for these proposals. Our board believes that, although the merger with ONI represents a complete change in the nature of our business, the merger affords our existing shareholders an opportunity for future value that the board believes is currently unavailable given our existing technology. ONI develops, manufactures and markets dedicated-purpose magnetic resonance imaging systems, which, if the merger is consummated, will become the business of Novoste. Our financial advisor, Asanté Partners LLC, has delivered to the board of directors an opinion that the merger consideration to be paid by Novoste in the transaction is fair to us from a financial point of view. We anticipate that completion of the merger will result in the current holders of ONI's equity securities owning a majority of our common stock.

The accompanying proxy statement provides a detailed description of the proposed merger, and a copy of the merger agreement is attached to the proxy statement as *Annex A*. In addition, the proxy statement provides you with important information regarding our board of directors and the other proposals that require your vote. I urge you to read the proxy statement materials in their entirety and consider them carefully. Please pay particular attention to the Risk Factors beginning on page 13 for a discussion of the risks related to the merger.

It is important that your shares be represented at the special meeting, regardless of the size of your holdings. Accordingly, whether or not you expect to attend the special meeting, I urge you to vote promptly by returning the enclosed proxy card. You may revoke your proxy at any time

before it has been voted.

I look forward to seeing you on September 14, 2005.

Sincerely,

Alfred J. Novak

President and Chief Executive Officer

**The accompanying proxy statement is first being mailed or  
delivered to shareholders on or about August 8, 2005.**

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**Novoste Corporation**

**4350 International Boulevard**

**Norcross, Georgia 30093**

**(770) 717-0904**

**NOTICE OF SPECIAL MEETING OF SHAREHOLDERS**

**IN LIEU OF AN ANNUAL MEETING**

**TO BE HELD ON SEPTEMBER 14, 2005**

NOTICE IS HEREBY GIVEN that on September 14, 2005, Novoste Corporation will hold a special meeting of shareholders in lieu of an annual meeting at the JW Marriott Hotel Buckhead Atlanta, 3300 Lenox Road, Atlanta, Georgia. The meeting will begin at 9:00 a.m., local time.

At the special meeting, we will consider:

1. The issuance of shares of our common stock, par value \$0.01 per share, to the holders of equity securities of ONI Medical Systems, Inc., a privately held Delaware corporation, pursuant to the terms of an Agreement and Plan of Merger by and among us, ONIA Acquisition Corp. and ONI, dated May 18, 2005, under which ONI will become our wholly owned subsidiary;
2. An amendment to our amended and restated articles of incorporation to increase the authorized number of shares of our common stock from 25,000,000 to 75,000,000;
3. An amendment to our amended and restated articles of incorporation to change our name from Novoste Corporation to ONI Medical Systems, Inc.;
4. The election of two directors to our board of directors;
5. A proposal to adjourn the meeting to permit further solicitation of proxies; and
6. Any other business properly presented at the special meeting or any postponements or adjournments thereof.

The foregoing items of business are more fully described in the proxy statement accompanying this notice.

Pursuant to our by-laws, our board of directors has fixed July 15, 2005 as the record date for the determination of shareholders entitled to notice of and to vote at the special meeting and at all postponements or adjournments thereof. Only shareholders of record at the close of business on

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that date and eligible to vote will be entitled to vote at the special meeting and any postponements or adjournments thereof. A list of all shareholders entitled to vote at the special meeting will be open for examination by shareholders for any purpose related to the special meeting during ordinary business hours for a period of ten (10) days before the special meeting at our offices, located at 4350 International Boulevard, Norcross, Georgia, 30093.

By Order of the Board of Directors,

Daniel G. Hall

Corporate Secretary

Norcross, Georgia

August 4, 2005

***Whether or not you plan to attend the special meeting, please complete and return the enclosed proxy card. If you sign and return your proxy card without specifying a choice, your shares will be voted in accordance with the recommendations of our board of directors. You may, if you wish, revoke your proxy at any time before it is voted by filing with the Corporate Secretary of Novoste a written revocation or a duly executed proxy bearing a later date, or by attending the special meeting and voting in person.***

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**ANNEXES**

Annex A	Agreement and Plan of Merger
Annex B	Opinion of Asanté Partners LLC
Annex C	Novoste Share Increase Amendment
Annex D	Novoste Name Change Amendment

ONI (and Design) and OrthOne are registered trademarks of ONI Medical Systems, Inc. ONI Medical Systems, Inc. is a trademark of ONI Medical Systems, Inc.

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The following are some of the questions that you, as a shareholder of Novoste, may have and answers to those questions. These questions and answers, as well as the following summary, are not meant to be a substitute for the information contained in the remainder of this proxy statement, and this information is qualified in its entirety by the more detailed descriptions and explanations contained elsewhere in this proxy statement. We urge you to read this proxy statement in its entirety before making any decision as to your Novoste common stock.

**QUESTIONS AND ANSWERS ABOUT  
THE SPECIAL MEETING AND THE MERGER**

**Q: Why am I receiving this proxy statement?**

A: You are receiving this proxy statement for a special meeting of shareholders for two reasons. First, we have agreed to a business combination with ONI pursuant to the terms of the merger agreement that is described in this proxy statement. A copy of the merger agreement is attached to this proxy statement as *Annex A*. Second, the special meeting also is being held in lieu of our 2005 annual meeting of shareholders and, as such, you will be asked to elect two Class III directors and we will conduct at the special meeting such other business as would otherwise be conducted at our annual meeting.

In order to complete the merger, our shareholders must vote to approve (1) the issuance of our common stock pursuant to the merger agreement, (2) an amendment to our articles of incorporation to increase the number of authorized shares of our common stock, and (3) an amendment to our articles of incorporation to change our name from Novoste Corporation to ONI Medical Systems, Inc.

This proxy statement contains important information about the merger, the issuance of our common stock pursuant to the merger agreement, the proposed amendments to our articles of incorporation and the election of two class III directors. You should read it carefully.

Your vote is important. We encourage you to vote as soon as possible.

**Q: Has the Novoste board of directors made any recommendation regarding how to vote?**

A: Yes. Our board of directors has unanimously (with one director recused from the matters) determined that the merger with ONI and the related merger agreement are advisable, fair to and in the best interests of our shareholders, and has recommended that you vote in favor of the share issuance and the two amendments to our articles of incorporation. The reasons why our board recommends these proposals are discussed in greater detail in the section entitled *Approval of Issuance of Shares in the ONI Merger Recommendation of our Board of Directors and Reasons for the Merger*.

Our full board of directors has further unanimously approved, and recommended to you, the election of two Class III directors and the approval of the adjournment proposal.

**Q: Why is Novoste proposing the merger with ONI?**

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- A: In February 2005, we announced that our board of directors had determined that our vascular brachytherapy, or VBT, business, our only business line, was no longer viable and, as a result, the board had authorized a staged wind-down of the business. The board of directors also authorized the sale of the VBT business, which sale process is currently ongoing. The board determined that this decision was necessary in order to preserve the company's cash resources. While the sale process continues, Novoste will continue to actively sell its VBT products to its physician customers and accept new contracts. The board also announced in February 2005 that it was seeking new product opportunities, as well as a merger, business combination or other disposition of our business or assets. The merger agreement with ONI is the culmination of those efforts. We believe that the combination of Novoste and ONI affords our existing shareholders an

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opportunity for future value that in the board's opinion is currently unavailable given our existing technology. ONI is engaged in the development, manufacturing and marketing of dedicated-purpose magnetic resonance imaging systems, which, if the merger is completed, will become the business of Novoste.

### **Q: When and where is the special meeting of shareholders and who is entitled to vote?**

A: The special meeting of shareholders will take place at 9:00 a.m., local time, on September 14, 2005, at the JW Marriott Hotel Buckhead Atlanta, 3300 Lenox Road, Atlanta, Georgia. Holders of record of our common stock as of the close of business on July 15, 2005 are entitled to vote at the special meeting.

### **Q: What shareholder approvals are required to approve the share issuance in the ONI merger and the two amendments to Novoste's articles of incorporation?**

A: The affirmative vote of a majority of the total votes cast is required to approve the share issuance in the ONI merger. The approval of each of the two amendments to our articles of incorporation requires that the number of votes cast by shareholders at the special meeting in favor of the proposal exceed the number of votes cast against the proposal.

### **Q: What will happen in the ONI merger?**

A: Before entering into the merger agreement, we formed ONIA Acquisition Corp., which we refer to as Merger Sub. Merger Sub will merge with and into ONI, and ONI will continue as the surviving company. The surviving company will be our wholly owned subsidiary. Upon completion of the merger, each outstanding share of ONI common and preferred stock will be canceled and converted into the right to receive the number of shares of our common stock determined in accordance with the formulas set forth in the merger agreement. In addition, all outstanding and unexercised options and warrants to purchase shares of ONI equity securities will be assumed by us and be converted and become options and warrants to acquire shares of our common stock, also determined in accordance with these formulas.

The total number of shares of our common stock to be issued pursuant to the merger agreement (including upon exercise of assumed ONI options and warrants) will be determined at the time of the closing of the merger based on a formula that values us at the value of our net cash assets at closing and values ONI at \$20,000,000 (solely for purposes of this calculation). **We anticipate that completion of the merger will result in the current holders of ONI's equity securities owning a majority of our common stock.**

Based on 16,334,780 shares of our common stock outstanding on the record date, and assuming that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000, we currently expect to issue an aggregate of 22,720,304 shares of our common stock and to assume options and warrants to purchase an aggregate of 3,640,944 shares of our common stock if the merger is completed. Accordingly, we anticipate that the current holders of ONI's equity securities will have voting power sufficient to control all major corporate decisions immediately after the merger. See *Approval of Issuance of Shares in the ONI Merger* *Terms of the Merger Agreement* *Merger Consideration*.

### **Q: What will be the composition of Novoste's board of directors after the merger?**

A: Immediately following the merger, our board of directors will consist of nine directors, five of whom have been designated by ONI and four of whom have been or will be designated by us. One of the five ONI designees will be Alfred J. Novak, who is currently our chief executive officer and one of our directors. Mr. Novak will resign from his management position at the closing of the merger. One of our four designees will be Stephen I. Shapiro, who is currently a director of both Novoste and ONI. See *Approval of Issuance of Shares in the ONI Merger* *Terms of the Merger Agreement* *Board of Directors of the Combined Company*.



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**Q: Who will be Novoste's largest shareholder after the merger?**

A: Based on 16,334,780 shares of Novoste common stock outstanding on the record date, and assuming that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000, we expect that Galen Partners IV, LP and affiliated entities, who are currently shareholders of ONI, will beneficially own approximately 31% of our common stock outstanding immediately after the merger. For information about the percentage ownership our largest shareholders will have in the combined company, see [Approval of Issuance of Shares in the ONI Merger](#) [Pro Forma Security Ownership of Novoste Following the Merger](#).

**Q: What will I receive for my shares in the merger?**

A: Our shareholders will not be exchanging their shares in the merger. Upon completion of the merger, you will continue to own the same number of shares of our common stock that you owned immediately before the merger. Because we will issue shares to the current holders of ONI's equity securities, however, the percentage ownership interest that your shares represent in us will be reduced.

**Q: What are the U.S. federal income tax consequences of the merger to me?**

A: We and ONI intend for the merger to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code. As a result, the merger is not expected to have any U.S. federal income tax consequences for our current shareholders. See [Approval of Issuance of the Shares in the ONI Merger](#) [Material U.S. Federal Income Tax Consequences of the Merger](#).

**Q: Why am I being asked to approve amendments to Novoste's articles of incorporation?**

A: The amendments to our articles of incorporation are necessary in order for us to complete the merger. For example, if our shareholders do not approve the share increase proposal, we will not have enough shares authorized to issue our common stock to ONI's shareholders as contemplated by the merger agreement.

**Q: Are there risks I should consider in deciding whether to vote to approve the issuance of Novoste shares pursuant to the merger agreement?**

A: Yes. In evaluating the issuance of shares of our common stock pursuant to the merger agreement, you should carefully consider the factors discussed in [Risk Factors](#) beginning on page 13 and the other matters discussed in this proxy statement.

**Q: How do I cast my vote if I am a holder of record?**

A: After carefully reading and considering the information contained in this proxy statement, if you are a holder of record, you may vote in person at the special meeting or by submitting a proxy for the meeting. You can submit your proxy by completing, signing, dating and returning the enclosed proxy card in the accompanying pre-addressed, postage-paid envelope.

IF YOU SIGN, DATE AND SEND YOUR PROXY AND DO NOT INDICATE HOW YOU WANT TO VOTE, YOUR PROXY WILL BE VOTED FOR EACH PROPOSAL DESCRIBED IN THIS DOCUMENT, INCLUDING THE ISSUANCE OF SHARES OF OUR COMMON STOCK PURSUANT TO THE MERGER AGREEMENT AND THE AMENDMENTS TO OUR ARTICLES OF INCORPORATION.

**Q: If my shares are held in street name, will someone else vote my shares for me?**

A: If you hold your shares in street name, which means your shares are held of record by a broker, bank or nominee, you must provide the record holder of your shares with instructions on how to vote your shares. If you do not provide your broker, bank or nominee with instructions on how to vote your shares, such person or entity may not be permitted to vote your shares.

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**Q: Can I change my vote after I have delivered my proxy?**

A: Yes. If you are a record holder, you can change your vote at any time before your proxy is voted at the special meeting by delivering a later-dated, signed proxy card to our company secretary before the meeting or by attending the meeting and voting in person. You also may revoke your proxy by delivering, before the date of the meeting, a notice of revocation to our company secretary at 4350 International Boulevard, Norcross, Georgia 30093 (attn: Daniel Hall, Esq.).

**Q: What should I do if I receive more than one set of voting materials?**

A: You may receive more than one set of voting materials, including multiple copies of this document and multiple proxy cards or voting instruction cards. For example, if you hold your shares in more than one brokerage account, you will receive a separate voting instruction card for each brokerage account in which you hold shares. If you are a holder of record and your shares are registered in more than one name, you will receive more than one proxy card. Please complete, sign, date and return each proxy card and voting instruction card that you receive.

**Q: Where will my shares of common stock be listed after completion of the merger?**

A: Our common stock is currently listed on the Nasdaq National Market. However, on April 21, 2005, we received a notice from Nasdaq indicating that we were not in compliance with the Nasdaq Stock Market's requirements for continued listing because, for the previous 30 consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under Nasdaq Marketplace Rule 4450(a)(5). We have until October 18, 2005, to achieve compliance with the minimum requirements for continued listing. If we do not regain compliance with the minimum requirements for continued listing by October 18, 2005, the Nasdaq staff will provide us with written notification that our common stock will be delisted from the Nasdaq National Market.

In addition, we have been preliminarily informed by the Nasdaq staff that our merger with ONI will constitute a change of control transaction, or reverse merger, requiring us to meet the Nasdaq National Market's initial listing requirements at the time of closing. These requirements include that our shareholders' equity immediately after the merger exceeds \$30 million, and that our common stock satisfies a \$5 per share minimum bid price immediately after closing. We have determined that our shareholders' equity immediately after the merger would not satisfy this requirement. As a result, if we are unable to convince the Nasdaq staff that the merger does not constitute a reverse merger, we anticipate that our common stock will be unable to remain listed on the Nasdaq National Market after the merger. If we are unable to retain the listing of our common stock on the Nasdaq National Market, we and ONI intend to attempt to obtain a new listing on the Nasdaq SmallCap Market or American Stock Exchange, or alternatively, the NASD's OTC Bulletin Board.

**Q: When does Novoste expect to complete the merger?**

A: We currently expect to complete the merger during the third calendar quarter of 2005.

**Q: Should I send in my share certificates?**

A: No. Your share certificates will not be exchanged in connection with the merger.

**Q: Do I have appraisal rights?**

A: No. Our shareholders do not have appraisal rights under Florida law in connection with the merger.



**Q: Who can help answer my questions?**

A: If you have any questions about the merger, the issuance of shares pursuant to the merger agreement, the amendments to our articles of incorporation or any of the other proposals, or about how to submit your

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proxy, or if you need additional copies of this document or the enclosed proxy card, you should contact either:

Novoste Corporation		Morrow & Co., Inc.
4350 International Boulevard		445 Park Avenue
Norcross, Georgia 30093	or	New York, New York 10022
Attention: Daniel G. Hall, Esq., General Counsel		Phone: (800) 654-2468
Phone: (770) 717-0904		

**Q: Where can I find more information about the companies?**

A: You can find more information about us from various sources described under [Where You Can Find More Information](#). Because ONI is a private company that does not file reports with the SEC, there is limited information publicly available about ONI, other than what has been provided in this proxy statement.

**Q: How may this proxy be solicited and who is bearing the cost of this proxy solicitation?**

A: Proxies may be solicited on behalf of our board of directors by mail, telephone, facsimile or electronic communication or in person and we will pay the solicitation costs, which include the cost of printing and distributing proxy materials and soliciting of votes. Our directors, officers and employees may solicit proxies by such methods without additional compensation. In addition, we have retained Morrow & Co., Inc. to assist us in the solicitation of proxies at an estimated cost of up to \$50,000 plus expenses. We also will reimburse brokerage houses and other custodians, nominees and fiduciaries for their reasonable out-of-pocket expenses for forwarding proxy and solicitation materials to shareholders.

\* \* \* \* \*

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**SUMMARY TERM SHEET**

Annual Meeting Time and Date	9:00 a.m., local time, on September 14, 2005
Annual Meeting Location	JW Marriott Hotel Buckhead Atlanta 3300 Lenox Road Atlanta, Georgia
Record Date	July 15, 2005
<i>Proposal 1</i> The Issuance of Shares in the ONI Merger	
The ONI Merger	Our wholly owned subsidiary, ONIA Acquisition Corp., will merge with and into ONI Medical Systems, Inc. As a result, ONI will become our wholly owned subsidiary.

The Share Issuance

We are asking our shareholders to approve the issuance of shares of our common stock to the holders of ONI capital stock, as well as the issuance of shares of our common stock upon the exercise of the options and warrants that we will assume from ONI. The total number of shares of our common stock to be issued if the merger is completed (including upon exercise of assumed ONI options and warrants) will be determined at the time of the closing of the merger based on a formula that values us at the value of our net cash assets at closing and values ONI at \$20,000,000 (solely for purposes of this calculation). **We anticipate that completion of the merger will result in the current holders of ONI's equity securities owning a majority of our common stock.**

Based on 16,334,780 shares of our common stock outstanding on the record date, and assuming that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000, we currently expect to issue an aggregate of 22,720,304 shares of our common stock, and to assume options and warrants to purchase an aggregate of 3,640,944 shares of our common stock, if the merger is completed. Accordingly, we anticipate that the current holders of ONI's equity securities will have voting power sufficient to control all major corporate decisions immediately after the merger. See *Approval of Issuance of Shares in the ONI Merger* Terms of the Merger Agreement Merger Consideration.

We have been preliminarily informed by the Nasdaq staff that our merger with ONI will constitute a change of control transaction, or reverse merger, requiring us to meet the Nasdaq National Market's initial listing requirements at the time of closing. These requirements include that our shareholders' equity immediately after the merger exceeds \$30 million, and that our common stock satisfies a \$5 per share minimum bid price immediately after closing. We have determined that our shareholders' equity immediately after the merger would not satisfy this requirement. As a result, if we are unable to



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convince the Nasdaq staff that the merger does not constitute a reverse merger, we anticipate that our common stock will be unable to remain listed on the Nasdaq National Market after the merger. If we are unable to retain the listing of our common stock on the Nasdaq National Market, we and ONI intend to attempt to obtain a new listing on the Nasdaq SmallCap Market or American Stock Exchange, or alternatively, the NASD's OTC Bulletin Board.

**Required Vote** The affirmative vote of a majority of the total votes cast is required to approve the issuance of our shares pursuant to the merger agreement. See 2005 Annual Meeting of Shareholders Required Vote; Broker Voting Procedures.

**Conditions to Closing** The conditions to the ONI merger include the approval by our shareholders of the issuance of shares of our common stock pursuant to the merger agreement, an amendment to our articles of incorporation to increase our authorized common stock, an amendment to our articles of incorporation to change our name from Novoste Corporation to ONI Medical Systems, Inc., and other conditions described in Approval of Issuance of Shares in the ONI Merger Terms of the Merger Agreement Conditions to Complete the Merger.

**Fairness Opinion** Asanté Partners LLC, an investment banking firm, has given its opinion, dated May 16, 2005, to our board of directors that the consideration to be paid in connection with the ONI merger is fair from a financial point of view to us. See Approval of Issuance of Shares in the ONI Merger Opinion of our Financial Advisor.

**U.S. Federal Income Tax Consequences** We and ONI intend for the merger to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code. As a result, the merger will have no U.S. federal income tax consequences for us or our current shareholders. See Approval of Issuance of Shares in the ONI Merger Material U.S. Federal Income Tax Consequences of the Merger.

**Business of Novoste After the Merger** Upon completion of the merger, our business will be ONI's business, namely, the development, manufacturing and marketing of dedicated-purpose magnetic resonance imaging systems.

**The Board of Directors and Management of Novoste after the Merger** Upon completion of the merger, the existing management of ONI will become our management and our board of directors will consist of nine directors, five of whom have been designated by ONI and four of whom have been or will be designated by us.

**Proposal 2 An Increase in the Number of Authorized Shares of Novoste Common Stock** In order for us to issue the shares of our common stock to the holders of ONI capital stock at closing and to reserve a sufficient number of

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shares for issuance upon the exercise of options and warrants we will assume if the merger is completed, we must first amend our articles of incorporation to increase the number of shares of common stock that we are authorized to issue. Our board of directors is recommending that our shareholders approve the proposed amendment to increase the number of authorized shares of common stock from 25,000,000 to 75,000,000

Required Vote

In order to approve the proposal to increase the number of authorized shares of our common stock, the number of votes cast by shareholders at the special meeting in favor of the proposal must exceed the number of votes cast against the proposal.

*Proposal 3* A Change in the Name of Novoste Corporation to ONI Medical Systems, Inc.

The ONI merger represents a complete change in the nature of our business. Because of this change, we agreed in the merger agreement that our name after the merger should be ONI Medical Systems, Inc. Our board of directors is recommending that our shareholders approve the proposed amendment to our articles of incorporation to change our name from Novoste Corporation to ONI Medical Systems, Inc.

Required Vote

In order to approve the proposal to change our name to ONI Medical Systems, Inc., the number of votes cast by shareholders at the special meeting in favor of the proposal must exceed the number of votes cast against the proposal.

*Proposal 4* Election of Two Directors to our Board of Directors

Our board of directors has nominated Thomas D. Weldon and Charles E. Larsen, whose terms will expire at the special meeting in lieu of an annual meeting, for re-election to our board of directors as Class III directors for terms expiring at the annual meeting in 2008. If we complete the ONI merger, however, Mr. Weldon and two of our other directors, J. Stephen Holmes and William E. Whitmer, will resign and five new directors will be added to our board as described in *Approval of Issuance of Shares in the ONI Merger Terms of the Merger Agreement Board of Directors of the Combined Company*.

Required Vote

A plurality of the total votes cast is required to elect each of the two directors.

*Proposal 5* The Adjournment Proposal

We are asking our shareholders to authorize the holder of the proxy solicited by our board of directors to vote in favor of adjourning the special meeting to a future date in order to enable our board of directors to solicit additional proxies in favor of the share issuance and the two proposed amendments to our articles of incorporation if such a proposal is presented at the special meeting.

Required Vote

In order to approve this proposal, the number of votes cast by shareholders at the special meeting in favor of the proposal must exceed the number of votes cast against the proposal.

**Table of Contents****SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA OF NOVOSTE**

The summary consolidated 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 proxy statement. The summary consolidated financial data shown below for the fiscal quarters ended March 31, 2005 and 2004, and as of March 31, 2005, have been taken or derived from our unaudited financial statements included in this proxy statement. In the opinion of management, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the results of the interim periods. Operating results for the three months ended March 31, 2005 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2005. The summary consolidated financial data shown 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 proxy statement. The summary consolidated financial data shown below should be read in conjunction with the consolidated financial statements and related notes of Novoste and with Novoste Management's Discussion and Analysis of Financial Condition and Results of Operations, which are included elsewhere in this proxy statement.

	Three Months Ended		Year Ended December 31				
	March 31						
	2005 (1)	2004	2004	2003	2002	2001	2000
(In thousands, except per share amounts)							
<b>Consolidated Statement of Operations Data:</b>							
Net sales	\$ 3,413	\$ 7,025	\$ 23,268	\$ 62,901	\$ 69,030	\$ 69,908	\$ 6,530
Cost and expenses:							
Cost of sales	4,118	3,953	16,111	24,315	27,313	19,164	4,258
Impairment and related charges			9,349		6,900		
Research and development	434	2,475	4,633	11,986	13,300	12,756	17,119
Sales and marketing	2,702	3,489	12,558	19,485	26,875	35,868	15,651
General and administrative	2,878	1,800	8,036	8,237	8,335	9,324	6,321
Loss from operations	(6,719)	(4,692)	(27,419)	(1,122)	(13,693)	(7,204)	(36,819)
Other income	165	78	498	254	642	2,095	3,746
Net loss	\$ (6,554)	\$ (4,614)	\$ (26,921)	\$ (868)	\$ (13,051)	\$ (5,109)	\$ (33,073)
Basic and diluted net loss per share	\$ (0.40)	\$ (0.28)	\$ (1.65)	\$ (0.05)	\$ (0.80)	\$ (0.32)	\$ (2.13)
Weighted average shares outstanding	16,335	16,331	16,333	16,313	16,268	16,152	15,517

	At March 31,		At December 31			
	2005 (1)	2004	2003	2002	2001	2000
(In thousands)						
<b>Consolidated Balance Sheet Data:</b>						
Working capital	\$ 19,618	\$ 25,753	\$ 39,364	\$ 30,496	\$ 40,482	\$ 53,742
Total assets	27,043	33,702	61,407	67,520	82,911	77,073
Long-term liabilities				5	203	401
Accumulated deficit	(168,777)	(162,223)	(135,302)	(134,434)	(121,384)	(116,275)
Total shareholders' equity	19,806	26,454	53,244	52,765	64,728	67,042

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- (1) On February 22, 2005, we announced that our board of directors had determined that our vascular brachytherapy business, which is our only business line, is no longer viable and, as a result, had authorized a staged wind-down of the business. As described in the notes to our financial statements, assets have been stated at estimated net realizable value and accruals have been recorded to reflect the business assumptions of the wind-down in accordance with FAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*.



**Table of Contents****SUMMARY HISTORICAL FINANCIAL DATA OF ONI**

The summary 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 ONI's audited financial statements included in this proxy statement. The summary financial data shown below for the fiscal quarters ended March 31, 2005 and 2004, and as of March 31, 2005, have been taken or derived from ONI's unaudited financial statements included in this proxy statement. In the opinion of ONI's management, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the results of the interim periods. Operating results for the three months ended March 31, 2005 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2005. The summary financial data shown below for the fiscal years ended December 31, 2001 and 2000, and as of December 31, 2002, 2001 and 2000, have been derived from ONI's financial statements for those years, which are not included in this proxy statement. The summary financial data shown below should be read in conjunction with the financial statements and related notes of ONI and with ONI Management's Discussion and Analysis of Financial Condition and Results of Operations, which are included elsewhere in this proxy statement.

	Three Months Ended March 31		Year Ended December 31				
	2005	2004	2004	2003	2002	2001	2000
(In thousands, except per share amounts)							
<b>Consolidated Statement of Operations Data:</b>							
Total revenue	\$ 2,629	\$ 655	\$ 8,887	\$ 8,297	\$ 6,276	\$ 725	\$
Total cost of revenue	2,125	758	7,826	5,761	4,752	1,358	
Gross profit (loss)	504	(103)	1,061	2,536	1,524	(633)	
Research and development	602	466	1,843	1,783	2,328	1,766	1,534
Sales and marketing	977	963	3,392	2,291	1,894	1,300	234
General and administrative	515	443	1,822	1,314	1,255	1,242	936
Loss from operations	(1,590)	(1,975)	(5,996)	(2,852)	(3,953)	(4,941)	(2,704)
Other income (expense)		25	(4)	(206)	(188)	67	90
Net loss	\$ (1,590)	\$ (1,950)	\$ (6,000)	\$ (3,058)	\$ (4,141)	\$ (4,874)	\$ (2,614)
Basic and diluted net loss per share	\$ (0.27)	\$ (0.33)	\$ (1.01)	\$ (0.90)	\$ (2.06)	\$ (4.81)	\$ (2.86)
Weighted average shares outstanding	5,930	5,930	5,930	3,408	2,013	1,014	914

	At December 31					
	At March 31, 2005	2004	2003	2002	2001	2000
(In thousands)						
<b>Consolidated Balance Sheet Data:</b>						
Working capital (deficit)	\$ (1,794)	\$ 153	\$ 2,844	\$ (1,064)	\$ (290)	\$ (100)
Total assets	7,064	7,829	6,906	5,113	3,667	3,113
Long-term liabilities	660	397				
Redeemable convertible preferred stock	11,800	11,800	8,500			
Accumulated deficit	(25,397)	(23,807)	(17,806)	(14,552)	(10,411)	(5,537)
Total shareholder's equity (deficit)	(12,438)	(10,848)	(4,646)	88	758	552



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**SUMMARY UNAUDITED PRO FORMA COMBINED  
CONSOLIDATED FINANCIAL DATA OF ONI AND NOVOSTE**

The following summary unaudited pro forma combined consolidated financial data have been derived from and should be read together with the unaudited pro forma combined consolidated financial statements and related notes on pages 130 through 135, which are preliminary and have been prepared solely for purposes of developing the pro forma information. This information is based on our historical consolidated balance sheets and related historical consolidated statements of operations and those of ONI, and gives effect to the merger using the purchase method of accounting for business combinations, with ONI as the acquiring entity. Our historical statements of operations have been adjusted for the pro forma impact of the disposition or wind-down of our VBT business.

The following summary unaudited pro forma combined financial data are intended to provide you with a better description of what our operating results might have been had we completed the merger and disposed of or wound-down our VBT business as of January 1, 2004 for the statement of continuing operations data and as of March 31, 2005 for the balance sheet data. The data are for illustrative purposes only. Novoste and ONI may have performed differently had we always been combined. Further, the summary unaudited pro forma combined financial data do not reflect the full effect of restructuring charges that we will incur or costs related to the exiting of the VBT business. You should not rely on the summary unaudited pro forma combined financial data as being indicative of the historical results that would have been achieved had the companies always been combined or the financial position and operating results that the combined company will experience after the merger.

	Three Months Ended	Year Ended
	March 31, 2005	December 31, 2004
	(In thousands, except per share amounts)	
<b>Statement of Continuing Operations Data:</b>		
Revenues	\$ 2,629	\$ 8,887
Net loss	(1,850)	(7,214)
Net loss per share basic and diluted	(0.05)	(0.18)
<b>Balance Sheet Data:</b>		
Working capital	\$ 12,754	
Total assets	32,140	
Long-term liabilities	660	
Accumulated deficit	(30,606)	
Total shareholders' equity	13,691	

**Table of Contents****COMPARATIVE PER SHARE DATA**

Set forth below are net loss and book value per common share amounts for Novoste and ONI on a historical basis, for the combined company on a pro forma combined basis per Novoste common share and for the combined company on a pro forma combined basis per equivalent ONI common share. Neither we nor ONI paid a cash dividend during any of the periods presented below.

The pro forma combined data were derived by combining the adjusted historical consolidated financial information of Novoste and ONI using the purchase method of accounting for business combinations as described under Unaudited Pro Forma Combined Consolidated Financial Data of ONI and Novoste.

You should read the information below together with the consolidated financial statements and related notes of Novoste and ONI, Novoste Management's Discussion and Analysis of Financial Condition and Results of Operations, ONI Management's Discussion and Analysis of Financial Condition and Results of Operations, Selected Historical Consolidated Financial Data of Novoste and Selected Historical Financial Data of ONI included elsewhere in this proxy statement. The unaudited pro forma combined data below are for illustrative purposes only. The financial results may have been different had the companies always been combined. You should not rely on this information to be indicative of the historical results that would have been achieved had the companies always been combined or the future results that the combined company will experience after the merger.

	<b>Three Months Ended</b>	<b>Year Ended</b>
	<b>March 31, 2005</b>	<b>December 31, 2004</b>
<b>Novoste historical data, per common share:</b>		
Net loss - basic and diluted	\$ (0.40)	\$ (1.65)
Book value at end of period	1.21	1.62
<b>ONI historical data, per common share:</b>		
Net loss - basic and diluted	\$ (0.27)	\$ (1.01)
Book value at end of period	(2.10)	(1.83)
<b>Combined consolidated pro forma data, per Novoste common share:</b>		
Net loss - basic and diluted	\$ (0.05)	\$ (0.18)
Book value at end of period	0.35	
<b>Combined consolidated pro forma data, per equivalent ONI common share:</b>		
Net loss - basic and diluted	\$ (0.06)	\$ (0.21)
Book value at end of period	0.41	

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**RISK FACTORS**

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 us or on our behalf, 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.

In addition to the other information included in this proxy statement (including the matters addressed in *Cautionary Note Regarding Forward-Looking Statements* ), you should consider carefully the matters described below in evaluating the proposed merger and the other proposals on which the merger is contingent, as well as our business, the business of ONI and the proposed business of the combined company. Additional risks and uncertainties that are not presently known to us or ONI or that we do not currently believe to be important to you also may adversely affect our respective businesses, the merger or the combined business following the merger.

**Risks Related to the Merger and the Combined Company**

*The market price of our common stock may fluctuate significantly, and may be less than the market price of our common stock as of the date of the merger agreement, this proxy statement or the special meeting.*

At the closing of the merger, all ONI equity securities will be converted into the right to receive shares of our common stock. The ratios at which ONI equity securities will be converted will not be adjusted for changes in the value of ONI or the market price of our common stock. We cannot abandon the merger or resolicit the vote of our shareholders solely because of changes in the value of ONI or the market price of our common stock.

The market price and trading volume of our common stock may vary significantly between the dates of the merger agreement, this proxy statement, the special meeting and the completion of the merger. These variations may be caused by, among other factors, responses to the risk factors described in this proxy statement, market expectations of the likelihood that the merger will be completed and the timing of its completion, the market's perception of the merits of the merger, or the prospects for our post-merger operations, or for reasons unrelated to our performance, such as reports by industry analysts, investor perceptions, or announcements by our or ONI's customers, competitors or suppliers regarding their own performance, as well as general economic and industry conditions. Accordingly, the trading price of our common stock now or on the date of the special meeting may not be indicative of the price of our common stock after the merger is completed. There can be no assurance that the market price or the trading volume of our common stock after the merger will be at or above the market price and trading volume of our common stock on the date of the merger agreement, this proxy statement, the special meeting or the closing.

*We and ONI will incur significant costs in connection with the merger, whether or not we complete it.*

We and ONI expect to incur significant costs related to the merger. These expenses include financial advisory, legal and accounting fees and expenses, severance and employee benefit related expenses, filing fees, printing expenses, proxy solicitation and other related charges. We and ONI may also incur additional unanticipated expenses in connection with the merger. A portion of the costs related to the merger, such as legal

and accounting fees, will be incurred regardless of whether the merger is completed. These expenses will reduce the assets that the combined company will have to operate its business after the merger.

***Completion of the merger will result in substantial and immediate dilution to the voting power and equity interests of our current shareholders.***

The issuance of shares of our common stock and options and warrants to purchase shares of our common stock to the holders of ONI equity securities if the merger is completed will significantly dilute the voting power

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and ownership percentage of our existing shareholders. The total number of shares of our common stock to be issued if the merger is completed (including upon exercise of assumed ONI options and warrants) will be determined at the closing based on a formula that values us at the value of our net cash assets at closing and values ONI at \$20,000,000 (solely for purposes of this calculation). We anticipate that completion of the merger will result in the current holders of ONI's equity securities owning a majority of our common stock.

Based on 16,334,780 shares of our common stock outstanding on the record date, and assuming that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000, we currently expect to issue an aggregate of 22,720,304 shares of our common stock at closing and to assume options and warrants to purchase an aggregate of 3,640,944 shares of our common stock. Accordingly, we anticipate that the current holders of ONI's equity securities will have voting power sufficient to control all major corporate decisions immediately after the merger. See Approval of Issuance of Shares in the ONI Merger Terms of the Merger Agreement Merger Consideration.

***If the combined company continues to experience losses after the merger, it could experience difficulty meeting its business plan, and our stock price could be negatively affected.***

During 2004 we had net losses of \$26.9 million and negative cash flow from operations of \$6.3 million, and ONI had net losses of \$6.0 million and negative cash flow from operations of \$5.2 million. After the merger, it is expected that the combined company will continue to experience operating losses and negative cash flow from operations. Any failure to achieve and then maintain profitability and positive cash flow could negatively impact the market price of our common stock and our ability to continue as a going concern. ONI has not been profitable or cash flow positive on a quarterly or annual basis. As a result, the combined company will need to generate significant quarterly revenues if it is to achieve profitability and positive cash flow. A failure to achieve profitability or positive cash flow could make it difficult or impossible for the combined company to grow its business. If its business strategy is not successful, it may not generate significant revenues or achieve profitability.

***The combined company may need additional funds which, if available, could result in increased interest expenses or additional dilution to our shareholders. If additional funds are needed and are not available, the business of the combined company could be negatively impacted.***

If we need to raise additional funds, we may not be able to do so on terms favorable to us, or at all. The combined company may need to seek higher-priced financing, modify or abandon its growth strategy or eliminate product and service offerings, any of which could negatively impact the combined company's financial position. If funds are raised through the issuance of equity securities, the percentage ownership of our then-current shareholders will be reduced and the holders of new equity securities may have rights, preferences or privileges senior to those of the holders of our common stock. If additional funds are raised through a bank credit facility or the issuance of debt securities, the holder of such indebtedness would have rights senior to the rights of common shareholders and the terms of such indebtedness could impose restrictions on our operations.

***After the merger, our board of directors will consider the filing of a registration statement with the SEC to register the resale of the shares of our common stock issued under the merger agreement, and the availability of these shares for sale in the public markets may cause a significant drop in the market price of our common stock.***

Based on 16,334,780 shares of our common stock outstanding on the record date, and assuming that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000, we currently expect to issue an aggregate of 22,720,304 shares of our common stock at closing and to assume options and warrants to purchase an aggregate of 3,640,944 shares of our common stock. After the merger, our board of directors will consider the filing of a registration statement with the SEC to register for resale in the public markets shares of our common stock issued under the merger agreement, as well as one or more registration statements on Form S-8 to register shares of our common stock issuable

pursuant to assumed options. Sales of a substantial number of these shares of our common stock, or the perception that such sales could occur, could adversely affect the market price of our common stock.



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*After the merger, the former principal shareholders of ONI will have significant influence over Novoste.*

Based on assumptions described elsewhere in this proxy statement, including the assumption that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000, we anticipate that Galen Partners IV, LP and its affiliates, who currently control ONI, will beneficially own approximately 31% of our common stock outstanding immediately after the merger. As a result, these principal shareholders of ONI will possess significant influence over our affairs after the merger. Under the merger agreement, Bruce F. Wesson and Srini Conjeevaram, the managing director and general partner of Galen Partners IV, LP, respectively, will become members of our board of directors after the merger. In addition, Stephen I. Shapiro, an independent consultant to Galen Partners IV, LP, will continue as a member of our board of directors after the merger. Galen Partners' stock ownership and relationships with members of our board of directors may have the effect of delaying or preventing a future change in control, impeding a merger, consolidation, takeover or other business combination or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could materially and adversely affect the market price of our common stock. If our net cash assets are \$11,750,000 or less at closing, we currently anticipate that Galen Partners IV, LP and its affiliates will beneficially own between approximately 32% and 34% of our common stock outstanding immediately after the merger.

*We may be unable to maintain an established public trading market after the merger, which would adversely affect your ability to sell your shares.*

Although our common stock is currently listed on the Nasdaq National Market, a regular trading market for our common stock may not exist or be sustained in the future, in which case you should consider your investment in our common stock illiquid. On April 21, 2005, we received a notice from the Nasdaq Stock Market indicating that we were not in compliance with the Nasdaq Stock Market's requirements for continued listing because, for the previous 30 consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under Nasdaq Marketplace Rule 4450(a)(5). We have until October 18, 2005, to achieve compliance with the minimum requirements for continued listing. If we do not regain compliance with the minimum requirements for continued listing by October 18, 2005, the Nasdaq staff will provide us with written notification that our common stock will be delisted from the Nasdaq National Market. In addition, we have been preliminarily informed by Nasdaq staff that our merger with ONI will constitute a change of control transaction, or reverse merger, requiring us to meet Nasdaq's initial listing requirements at the time of closing. These requirements include that our shareholders' equity immediately after the merger exceeds \$30 million, and that our common stock satisfies a \$5 per share minimum bid price immediately after closing. We have determined that our shareholders' equity immediately after the merger would not satisfy this requirement. As a result, if we are unable to convince Nasdaq staff that the merger does not constitute a reverse merger, we anticipate that our common stock will be unable to remain listed on the Nasdaq National Market after the merger.

If we are unable to retain the listing of our common stock on the Nasdaq National Market, we and ONI intend to attempt to obtain a new listing on the Nasdaq SmallCap Market or American Stock Exchange. To obtain a new listing on the Nasdaq SmallCap Market, we anticipate that our common stock will need to satisfy a \$4 per share minimum bid price requirement immediately after closing. To obtain a new listing on the American Stock Exchange, we anticipate that our common stock will need to satisfy either a \$3 per share minimum bid price requirement or a \$50 million market capitalization requirement immediately after closing. Based on the recent trading price of our common stock, we do not anticipate that our common stock would be able to satisfy either of these requirements unless we completed a reverse share split, in which shares of our common stock would be combined to increase the percentage ownership interest that each share represents. Our board of directors is permitted under Florida law to authorize a reverse share split without the approval of our shareholders, and may consider authorizing such a split to obtain a listing on the Nasdaq SmallCap Market or American Stock Exchange.

If we are unable to retain our listing on the Nasdaq National Market, or obtain a new listing on the Nasdaq SmallCap Market or American Stock Exchange, we may seek to have our stock quoted on the NASD's OTC



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Bulletin Board, which is an inter-dealer, over-the-counter market that provides significantly less liquidity than the Nasdaq National Market, Nasdaq SmallCap Market or American Stock Exchange. Quotes for stocks included on the OTC Bulletin Board are not as widely listed in the financial sections of newspapers as are those for the Nasdaq National Market. Therefore, prices for securities traded solely on the OTC Bulletin Board may be difficult to obtain and holders of our common stock may be unable to resell their securities at any price.

***If we move trading of our common stock to the NASD's OTC Bulletin Board, our common stock will be a penny stock and may be difficult to sell.***

If we move trading of our common stock to the NASD's OTC Bulletin Board, our common stock will be a penny stock under Rule 3a51-1 under the Securities Exchange Act of 1934. Compliance with the penny stock requirements would make it more difficult for you to resell your shares to third parties or to dispose of them in the public market or otherwise. Securities broker-dealers would not be permitted to recommend our common stock and would be required to trade in it on an unsolicited basis. Additionally, Section 15(g) of the Exchange Act and Rule 15g-2 require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account. Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to:

obtain from the investor information concerning his or her financial situation, investment experience and investment objectives;

reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions;

provide the investor with a written statement setting forth the basis on which the broker-dealer made this determination; and

receive a signed and dated copy of this statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives.

***ONI is a private company and has not been subject to the same corporate governance standards as stock exchange or Nasdaq-listed companies, which may adversely affect the willingness of investors to buy or hold shares of the combined company's common stock.***

As a private company, ONI has not been subject to the enhanced corporate governance requirements applicable to companies whose securities are listed on a national securities exchange or with the Nasdaq Stock Market. Investors may lack confidence in the management of the combined company as management establishes and implements the enhanced corporate governance requirements of a public company. A lack of confidence in the combined company's management could lead to a substantial stock price decline.

***After the merger, the financial statements of the combined company will reflect substantially larger costs associated with compliance with laws and regulations affecting public companies, which will adversely affect the combined company's results of operations.***

## Edgar Filing: NOVOSTE CORP /FL/ - Form DEFM14A

For accounting purposes, ONI will be treated as the acquiring entity in the merger and, as a result, its historical financial statements will become the financial statements of the combined company. Because ONI has operated as a private company, it has not previously incurred the substantial accounting, legal and other expenses that the combined company will incur as a public company. After the merger, the financial statements of the combined company will reflect these substantial expenses, including costs associated with periodic reporting requirements under the Securities Exchange Act of 1934 and costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect that the

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rules and regulations applicable to public companies will increase the combined company's legal and financial compliance costs and will make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty.

*After the merger, ONI will be required for the first time to evaluate its internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, and any adverse results from such evaluation could result in a loss of investor confidence in the combined company's financial reports and lead to a substantial stock price decline.*

After the merger, the combined company will be required to furnish a report by its management on its internal control over financial reporting, including ONI's internal control over financial reporting. The report will contain, among other matters, an assessment of the effectiveness of ONI's internal control over financial reporting as of the end of the fiscal year, including a statement as to whether or not ONI's internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in ONI's internal control over financial reporting identified by management. The report must also contain a statement that the combined company's independent auditors have issued an attestation report on management's assessment of such internal controls.

ONI has not yet begun the process of analyzing its internal controls and preparing for the evaluation needed to comply with Section 404. During this process, if management identifies one or more material weaknesses in ONI's internal control over financial reporting that are not remediated, the combined company will be unable to assert that its internal control is effective. Any failure to have effective internal control over financial reporting could cause investors to lose confidence in the accuracy and completeness of the combined company's financial reports, which could lead to a substantial stock price decline.

*Management of the combined company does not intend to pay dividends.*

Neither Novoste nor ONI have ever declared or paid any cash dividends on its capital stock. The combined company anticipates that it will retain all future earnings, if any, to support its operations and to finance the growth and development of its business and therefore does not expect to pay cash dividends. Any return on an investment in the combined company will only be as a result of stock price appreciation, if any.

*The combined company could be the subject of securities class action litigation as a result of future stock price volatility, which could divert management's attention and adversely affect its results of operations.*

The stock market in general, and market prices for the securities of small medical device companies like ONI in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. We and ONI expect that the merger itself will create a certain degree of stock price volatility. These broad market and industry fluctuations may adversely affect the market price of the combined company's common stock, regardless of its operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the issuer. If any of the combined company's shareholders were to bring a lawsuit against it, the defense and disposition of the lawsuit could be costly and divert the time and attention of its management and harm its business.

## **Risks Related to Novoste's Business**

*If the merger with ONI is not completed, Novoste will have no continuing business operations.*

Our board of directors has authorized the staged wind-down of our VBT business, which is our only business line. We are currently implementing the wind-down, which we expect to complete before the end of the 2005. Should our shareholders not approve the proposals to allow us to complete the merger, we will have no ongoing business operations and our board of directors will need to consider other alternatives, including liquidation and dissolution.

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

Our board has authorized the staged wind-down of our VBT business 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. If we are unable to efficiently implement the wind-down of our business, our corporate assets may be further depleted.

***If the merger with ONI is not completed and 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 the merger with ONI is not completed and we were to liquidate and dissolve, we cannot predict when, or if, we would be able to make a distribution to our shareholders. However, if 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.

***If 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.***

If 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, before 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.

***If 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 Novoste.

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 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 even though compliance with such reporting requirements is economically burdensome. If



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the merger with ONI is not completed and we were to liquidate and dissolve, then 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. There can be no assurance that we would be able to obtain such relief.

*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.*

We currently have extremely limited personnel resources. 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, and terminating the 16 employees we had outside the U.S. in accordance with their contracts and the relevant country's employment regulations. We currently have 26 employees, 2 of whom are employed outside the U.S. If the merger with ONI is not completed, it may be difficult for us to efficiently implement the staged wind-down of our business.

*We are highly dependent on key management personnel.*

We are currently 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.

**Risks Related to ONI's Business**

*ONI has had and continues to experience significant losses.*

ONI has incurred operating losses since its inception and had an accumulated deficit of approximately \$25.4 million as of March 31, 2005. ONI incurred net losses of approximately \$3.1 million in 2003, \$6.0 million in 2004 and \$1.6 million in the three months ended March 31, 2005. ONI expects to continue to incur losses in the near future, and the amount of future losses is uncertain. There is no assurance that ONI will operate profitably in the foreseeable future or at all.

ONI intends to continue to make substantial investments in internal expansion, infrastructure, sales and marketing efforts and potential acquisitions. If ONI's revenues fail to grow at a sufficiently rapid pace to offset planned increases in expenses, or if ONI is unable to curb its losses and achieve profitability, its future growth could be seriously harmed.

*ONI has a limited operating history, which makes prediction of future results of operations difficult or impossible.*

ONI was incorporated in June 1997. ONI sold its first OrthOne® MRI system in the later half of 2001. As of June 30, 2005, ONI has sold and installed a total of only 70 OrthOne systems. Accordingly, ONI has a very limited operating history, which makes prediction of future results of operations difficult or impossible.

*Ernst & Young LLP, ONI's independent registered public accounting firm, issued its 2004 audit report with a going concern qualification, which raises substantial doubt about ONI's continued viability if ONI does not raise additional capital to fund its operations for the next twelve months.*

The audit report of ONI's independent auditors on ONI's 2004 financial statements included an explanatory paragraph expressing substantial doubt about ONI's ability to continue as a going concern. As of March 31,

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2005, ONI had negative working capital of approximately \$1.8 million and an accumulated deficit of approximately \$25.4 million, which reflect ONI's continued operating losses. ONI's financial statements do not include any adjustments that might be necessary to reflect this uncertainty accurately.

*Fluctuations in ONI's quarterly results make financial forecasting difficult and could lead to a substantial stock price decline.*

ONI has experienced significant fluctuations in its revenues and results of operations from one quarter to the next. ONI's quarterly revenue generally comprises only a small number of individual customer orders, and the timing of customer site readiness and revenue recognition for a single order can cause substantial fluctuations in ONI's quarterly results. Its future revenues and results of operations could vary significantly from quarter to quarter due to a number of factors, many of which are outside its control. These factors include changes in demand, customer site readiness and ONI's ability to deliver and install systems in a timely manner, warranty and service claims, the introduction of competing systems, customer budgetary cycles, sales incentives and other competitive pricing pressures. Accordingly, quarter-to-quarter comparisons of ONI's results of operations are not reliable indications of future performance. ONI's revenues or results of operations in a quarter may fall below the expectations of securities analysts or investors, which could lead to a substantial stock price decline.

*ONI's business depends on the successful commercialization of one product, the OrthOne 1.0 Tesla MRI system, and the market for high-field MRI systems for extremities is unproven.*

ONI's success depends on its ability to create a market for dedicated MRI systems for extremities. There may be limited market acceptance of such systems in general, or ONI's system in particular, among orthopedic practices, diagnostic imaging centers and hospitals. ONI's products may not enjoy commercial acceptance or success, which would adversely affect its revenues and results of operations. Because of the early stage of both ONI and the market for extremity MRI systems, it is likely that ONI's evaluation of the potential market demand for these products will vary materially with time. In addition, the introduction by other companies of new products or technologies that compete with ONI's system could reduce market acceptance or make ONI's system obsolete. ONI cannot assure that any significant or profitable market will develop for ONI's extremity MRI systems.

*ONI may not be able to compete effectively because ONI's competitors have far greater resources than ONI.*

ONI is a relatively new entrant in an intensely competitive market that is dominated by a small number of large, well-known companies. ONI's competitors have significantly greater financial, technical, manufacturing, marketing and managerial resources than ONI and might be perceived by customers as offering greater financial and operational stability than ONI. In the orthopedic market, ONI competes primarily with Esaote SpA, an Italian manufacturer of low-field extremity systems. In the hospital and diagnostic imaging center market, ONI competes with manufacturers of whole-body systems, including GE Medical Systems, Hitachi Corporation, Philips N.V., Siemens A.G. and Toshiba Corporation. There can be no assurance that these manufacturers of whole-body systems will not enter the market for extremity MRI systems. ONI may be unable to compete successfully against its current or future competitors, and competition may have a material adverse effect on ONI's business, results of operations and financial condition. ONI's competitors could develop MRI systems that are superior to that of ONI or that achieve greater market acceptance than ONI's system.

*ONI depends heavily on third-party suppliers, which makes it vulnerable to component part failures and to interruptions in supply.*

ONI relies on third-party suppliers for all key components used in its product, including the OrthOne magnet and certain software used to operate the OrthOne system. Relying on third-party suppliers makes ONI vulnerable to interruptions in supply, which could materially impair its ability to ship its product to customers on a timely basis and generate revenue. Generally, ONI does not have long-term supply agreements with its suppliers. Instead, ONI obtains supplies on a purchase-order basis. Lead times to receive ordered components

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vary and can exceed six months or more. If ONI expands its manufacturing capacity, it cannot be sure that its suppliers will furnish the required components when needed. These factors could make it more difficult for ONI to effectively and efficiently manufacture its product. As a result, ONI's sales may suffer.

***GE Medical Systems is currently ONI's sole supplier of the OrthOne magnet, and the loss of GE Medical Systems as a supplier could seriously harm ONI's revenues and results of operations.***

At present, ONI has only one supplier for the OrthOne magnet, GE Medical Systems. The manufacture of the OrthOne magnet is complex, and it would be difficult for ONI to identify, qualify, engage and train a new supplier in a short period of time. Under the agreement between ONI and GE Medical Systems, GE Medical Systems may cease accepting orders for the OrthOne magnet by providing ONI with at least 12 months written notice, in which case ONI would be entitled to place a final order for up to 1-½ times the number of magnets taken in the 12 months before the notice. After April 1, 2006, GE Medical Systems need not provide advance notice of cancellation. If GE Medical Systems were to cancel its supply agreement with ONI and at the time of cancellation ONI had no other supplier for the OrthOne magnet, ONI could face a shortage of OrthOne magnets, which would have a material adverse effect on ONI's ability to generate revenues. Moreover, ONI may be unable to negotiate favorable pricing with any new supplier, which could have a material adverse effect on ONI's results of operations and overall profitability. Finally, because GE Medical Systems, rather than ONI, has been manufacturing the OrthOne magnet for more than four years, ONI may encounter difficulties and delays in training another supplier to manufacture the magnet as efficiently and effectively as GE Medical Systems without its assistance.

***There is currently no ACR accreditation program for extremity MRI facilities, and some third-party payers may not offer reimbursement for MRI scans performed on the OrthOne system.***

The American College of Radiology, or ACR, a medical society for radiologists, has administered an accreditation program for whole-body MRI imaging systems since 1996. Several third-party payers have recognized the ACR accreditation program as a method of demonstrating quality in MRI scanning and reading of images, and require ACR accreditation for providers of MRI services. There is currently no ACR accreditation program for extremity MRI systems, and some third-party payers may not provide reimbursement for MRI scans performed on the OrthOne system, which could limit demand. More widespread adoption of the ACR accreditation program as a requirement for reimbursement could further limit demand and seriously harm our revenues and results of operations. Moreover, the ACR has endorsed the recommendations of the Medicare Payment Advisory Commission to set national standards for performing and interpreting diagnostic imaging studies covered by Medicare. The adoption of any such standards could make it more difficult for physicians other than radiologists to receive reimbursement for performing and interpreting diagnostic imaging studies, which could reduce demand for the OrthOne system and thereby reduce our revenues and results of operations.

***ONI may be unable to keep pace with the rapid technological changes in the MRI industry.***

The industry for magnetic resonance imaging equipment is characterized by extensive research and technological developments and advancements. Any failure by ONI to develop new or enhanced products for the medical marketplace could have a material adverse effect on its financial condition and results of operations. Development by other companies of new or improved products, processes or technologies may make the OrthOne system obsolete or less competitive. ONI's business could be seriously harmed by the introduction of extremity MRI systems with more attractive features, such as higher field strength, lower cost or smaller size. ONI will be required to devote material financial resources to develop and commercialize new products and technologies and to enhance the existing OrthOne system.

*ONI may not meet applicable regulatory requirements, and the failure to comply with any regulation could have serious consequences for ONI's ability to continue to operate its business.*

The manufacture and sale of medical diagnostic devices such as the OrthOne system are subject to extensive government regulation in the United States and in other countries. Federal, state and foreign laws and regulations

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impose numerous requirements on each aspect of the testing, manufacture, labeling, storage, recordkeeping, approval, advertising and promotion of the OrthOne system. Any enforcement action arising from ONI's failure to comply with any government regulation could result in warning letters, judicially and administratively imposed fines and penalties, suspensions of approvals, recalls of OrthOne systems, repairs, replacements, refunds, seizures, operating restrictions, denials of future approvals, withdrawals or suspensions of current product applications, and criminal prosecutions and could affect the manufacturing and marketing of the OrthOne system. Any of these outcomes could seriously harm ONI's reputation, revenues and results of operations, including a potential shutdown of ONI's operations.

Products such as the OrthOne system may be subject to government-mandated or voluntary recall for unforeseen reasons, including component failures, manufacturing errors or design defects. This risk exists even with respect to products with regulatory approval for commercial sale. Claims may be made by customers, patients, distributors, government regulators or others. ONI does not maintain any insurance relating to potential recalls.

The United States Food and Drug Administration, or FDA, as well as foreign regulatory agencies, continue to review products even after they have received initial regulatory approval. The manufacturing and marketing of these products will be subject to continuing regulation, including compliance with current Quality Systems Regulations and Good Manufacturing Practices, known as QSRs and GMPs, adverse event reporting requirements and prohibitions on promoting a product for unapproved uses. ONI's third-party suppliers of product components are also subject to compliance with the FDA requirements for QSR/GMP and other requirements. The FDA could withdraw a previously approved product such as the OrthOne system from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements, the occurrence of unanticipated problems with products following approval, or other reasons, any of which could adversely affect ONI's reputation, revenues, results of operations and financial condition.

***If ONI fails to obtain or maintain necessary FDA clearances for the OrthOne system or similar clearances in non-U.S. markets, or if such clearances are delayed, ONI will be unable to commercially distribute and market the OrthOne system.***

Before marketing any medical device in the United States, ONI must generally first receive clearance from the FDA, which is referred to as 510(k) clearance. This clearance process can be lengthy and expensive. The FDA's 510(k) clearance process generally takes less than six months from the date the application is submitted, but can take longer. Although ONI has obtained 510(k) clearance for the OrthOne system, its 510(k) clearance can be revoked if safety or effectiveness problems develop. ONI expects that its product currently under development will require 510(k) clearance. ONI may be unable to obtain additional clearances in a timely fashion or at all. Delays in obtaining clearance or the revocation of existing clearances could seriously harm ONI's revenues and profitability.

In many foreign countries in which ONI markets the OrthOne system, ONI is subject to regulations affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of these regulations are similar to those of the FDA. In addition, in many countries the national health or social security organizations require ONI's products to be qualified before procedures performed using its products become eligible for reimbursement. Failure to receive, or delays in the receipt of, relevant foreign qualifications could have a material adverse effect on ONI's business, financial condition and results of operations. Due to the evolving harmonization of standards in the European Union, ONI expects a changing regulatory environment in Europe characterized by a shift from a country-by-country regulatory system to a European Union-wide single regulatory system. ONI cannot predict changes of this harmonization and its effect on ONI. Adapting ONI's business to changing regulatory systems could have a material adverse effect on ONI's business, financial condition and results of operations.

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***Modifications to the OrthOne system may require new FDA clearance or similar clearances in non-U.S. markets or require ONI to cease marketing or recall the modified OrthOne system until these clearances are obtained.***

Any modification to a medical device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, generally requires a new FDA 510(k) clearance. Other countries have comparable regulatory requirements. The FDA requires every manufacturer to make this determination, but the FDA can review any such determination. ONI may make modifications to the OrthOne system, and in appropriate circumstances, determine that new clearance is unnecessary. The FDA may not agree with the decision not to seek new clearance. If the FDA requires that ONI seek 510(k) clearance for any modification not previously cleared, ONI may be required to cease marketing or recall the modified device until it obtains this clearance, which could seriously harm ONI's reputation, revenues and results of operations. Also, in some circumstances, such as the FDA's disagreement with the decision not to seek new clearance, ONI may be subject to significant regulatory fines or penalties.

***Reductions in third-party reimbursement may reduce market acceptance of ONI's products, resulting in lower sales in the United States and abroad.***

There has been a consistent downward trend for MRI reimbursement rates, and ONI anticipates that the trend will continue for the foreseeable future. This trend may result in lower sales in the United States and abroad.

ONI depends on third-party reimbursement to its customers for market acceptance of its products. Failure of third-party payors, such as the government or private health insurers, to provide appropriate levels of reimbursement for use of ONI's products would harm ONI's business and prospects. In the United States, Medicare reimbursement rates are established by the United States Department for Health and Human Services Centers for Medicare and Medicaid Services, or CMS, the government agency that administers Medicare and Medicaid. The actual reimbursement amounts are determined by individual state Medicare carriers and, for non-Medicare and Medicaid patients, by private insurance carriers. There are often delays between the reimbursement approvals by CMS and by a state Medicare carrier and private insurance carriers. Moreover, states as well as private insurance carriers may choose not to follow the CMS reimbursement guidelines.

The use of ONI's products outside the United States is similarly affected by reimbursement policies adopted by foreign regulatory and insurance carriers. A reduction or other adverse change in reimbursement policies for the use of ONI's products could harm ONI's business and prospects.

***The time needed to modify a customer facility may cause delays in shipping ONI's products and in recognizing revenue from sales of the products.***

The OrthOne system generally requires each customer to make some modifications to its facility before ONI installs the system. The cost and the amount of time needed to make the necessary modifications to a customer facility varies widely and depends completely on the customer. Historically, site preparation has taken from as little as one month to longer than one year. Delays in shipping and in revenue recognition resulting from site readiness could adversely affect ONI's revenues, results of operations and financial condition.

***ONI relies on distributors for its international sales, and ONI's failure to manage successfully its relationships with these distributors could cause its revenue to decline and harm its business.***



ONI relies on a number of distributors for its international sales, including sales in the European Union and Canada. These distributors also fulfill warranty and service obligations to customers outside the United States (except Canada). The activities of these distributors are not within ONI's direct control. ONI's failure to manage its relationships with these distributors effectively could impair the effectiveness of ONI's international sales, marketing and customer support strategy. A reduction in the sales efforts, technical capabilities or financial viability of these distributors, a misalignment of interest between ONI and them, or the termination of ONI's relationship with a distributor could adversely affect ONI's sales, financial results and ability to support its

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customers. ONI's distributors are engaged under long-term contracts, which typically have an initial term of four years. It generally takes three to six months for a distributor to become educated about ONI's products and capable of providing quality sales and technical support to ONI's customers. If any distribution relationship were to terminate, sales to current and prospective customers could be disrupted or delayed, and ONI could experience a diversion of time and resources as it seeks to identify, qualify, engage and train a replacement.

***ONI's business is highly dependent on its ability to successfully manufacture and assemble its products.***

ONI has manufactured and installed an aggregate of 70 units as of June 30, 2005, all of which require precise, high-quality manufacturing. Failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, design defects or component failures, could result in patient injury, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt ONI's business.

Despite its efforts, ONI cannot completely eliminate the risk of errors, defects or failures. The manufacturing of products is and will continue to be complex and costly, requiring a number of separate processes and components and skill and diligence by ONI's personnel and third-party suppliers. ONI may experience difficulties in manufacturing its product, including problems related to quality control and assurance, component and service availability, adequacy of control policies and procedures, and lack of skilled personnel. If ONI is unable to hire, train and retain enough experienced and capable scientific, technical and manufacturing workers, it may be unable to manufacture sufficient quantities of its products at an acceptable cost and on time, which could limit market acceptance of its products or otherwise damage ONI's financial performance and prospects.

***Significant unanticipated warranty or service claims could substantially increase ONI's costs and generate additional losses.***

If ONI experiences an increase in warranty or service claims, it could incur unanticipated expenditures for parts and service, which would adversely affect its results of operations. ONI generally warrants each of its products against defects in materials and workmanship for a period of one year. ONI has also entered into long-term service maintenance agreements with certain customers pursuant to which it has agreed to provide all necessary maintenance and services for a fixed fee. Although ONI has established reserves for its product warranty obligations, unforeseen warranty exposure in excess of those reserves could adversely affect its results of operations. In addition, any non-routine defects or operating problems could seriously damage ONI's reputation and goodwill in the market for MRI systems.

***ONI may be unable to retain its key personnel, which could adversely affect its ability to conduct its operations.***

ONI depends heavily on the principal members of its management and scientific staff. ONI does not have any employment agreements with any of its personnel. Accordingly, any of ONI's key personnel could resign immediately without notice to ONI, which could seriously harm ONI's ability to conduct its operations.

ONI depends upon the continued services of Robert L. Kwolyk, its co-founder and President and Chief Executive Officer since inception. Loss of his services could seriously harm ONI's business and prospects and its ability to market and sell the OrthOne system. Similarly, the services of Dr. Peter B. Roemer, the co-founder of ONI and its Senior Vice President and Chief Technology Officer, are integral to ONI's product development efforts. Loss of his services could result in material delay in ONI's development of new products.

*ONI may be unable to hire and retain the skilled personnel it needs to expand its operations.*

To meet its growth objectives, ONI must attract and retain additional highly skilled sales and marketing, managerial and technical personnel. If it fails to attract and retain the necessary personnel, it may be unable to achieve its business objectives and may lose its competitive position, which could lead to a significant decline in revenue. ONI faces significant competition for these skilled professionals from other companies and organizations.

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***In certain states, MRI systems can only be purchased through a Certificate of Need program, which may prohibit potential customers from purchasing the OrthOne system.***

Certificate of Need programs vary from state to state and are designed to ensure that new healthcare services and facilities are developed only as needed, based on publicly-developed measures of cost effectiveness, quality of care, and geographic and financial access to care. If state governments begin to make the acquisition of a Certificate of Need more difficult for ONI's potential customers or discourage sales of the OrthOne system in areas already served, ONI's sales will suffer, which could have a material adverse effect on ONI's revenues and results of operations.

***The market for used or refurbished whole-body MRI systems may limit ONI's growth.***

ONI relies on, among other things, its competitive pricing advantage when competing with whole-body MRI companies. It could become increasingly difficult for ONI to sell its products if other vendors expand their efforts to sell used or refurbished systems to ONI's potential customers. The continued growth of such a secondary market in used or refurbished MRI systems could seriously harm ONI's business, prospects and results of operations.

***ONI may enter into fee-for-scan programs, and the inability or refusal of any customer to pay required fees could adversely affect ONI's revenues and results of operations.***

On a limited basis, ONI offers a fee-for-scan program to selected customers. Under this program, customers have the option of paying for the OrthOne system on a per-scan basis. Non-payment by customers under this program could adversely affect ONI's financial results. ONI retains ownership of the system until all required payments are made. ONI has only a limited ability to evaluate potential customers and their creditworthiness. In the event of a breach of the agreement, ONI may encounter difficulties or significant expenses in attempting to repossess its systems. ONI may also have to accept the return of systems under this program.

***ONI has only limited protection for its intellectual property, and competitors could circumvent those protections.***

ONI's ability to compete effectively depends in part on its ability to protect the design of the OrthOne system and its other proprietary technology. The steps ONI has taken to protect its proprietary technology may be inadequate to prevent others from using what ONI regards as its technology to compete with ONI. Any misappropriation of ONI's technology or the development of competing technology could seriously harm ONI's competitive position, which could lead to a substantial reduction in revenue. ONI does not have any patents. ONI seeks to protect its proprietary technology primarily under laws affording protection for trade secrets and also seeks copyright and trademark protection for its products and developments where appropriate. These laws provide only limited protection. Confidentiality agreements with employees, consultants and other parties could be breached, ONI may not have adequate remedies for any breach, and ONI's trade secrets and other proprietary information could otherwise become known. In addition, other companies could independently develop technologies that are similar or superior to ONI's technology or reverse engineer its products. Moreover, the laws of foreign countries in which ONI sells its products may afford little or no protection to its intellectual property rights, which could increase the likelihood of misappropriation.

ONI may have to take legal action to protect its trade secrets or other proprietary information. Any legal action of that type could be burdensome, disruptive and expensive and distract the attention of management, and ONI might not prevail.

*Claims by others that ONI infringes their intellectual property rights could seriously harm ONI's business and financial condition.*

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Any claim of infringement against ONI could cause it to incur substantial costs

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defending against the claim, even if the claim is invalid, and could distract the attention of ONI's management. If ONI's products or technology is found to violate third-party proprietary rights, ONI may be required to pay substantial damages. In addition, ONI may be required to re-engineer its products or seek to obtain licenses from third parties to continue to offer its products. Any efforts to re-engineer its products or obtain licenses on commercially reasonable terms may not be successful, which would prevent ONI from selling its products, and, in any case, could substantially increase its costs and have a material adverse effect on its business, financial condition and results of operations.

ONI does not conduct comprehensive patent searches to determine whether other persons may have patents or patent applications that cover any portion of ONI's products or technology. In an evolving technological environment, product development is inherently uncertain, and there may be pending patent applications that may cover ONI's products or technology. Accordingly, other persons may have or obtain patents that will prevent, limit or interfere with ONI's ability to make, use or sell its products in the United States or international markets.

***If ONI is unable to maintain adequate product liability insurance, it may have to pay significant monetary damages in a successful product liability claim.***

The manufacture and sale of any diagnostic medical device such as the OrthOne system entail an inherent risk of product liability, including claims of injury from use of the system or the failure to detect a disorder. If ONI is exposed to product liability claims for which it has insufficient insurance, it may be required to pay significant damages, which could seriously harm its financial condition and results of operations. Product liability insurance is generally expensive for companies such as ONI. Accordingly, ONI maintains only limited product liability insurance coverage. ONI's current levels of insurance or any insurance it may subsequently obtain may not provide adequate coverage against potential claims. In addition, ONI may be unable to renew its policies on commercially reasonable terms or obtain additional product liability insurance on acceptable terms, if at all. Any product liability claim brought against ONI, regardless of merit, could increase ONI's product liability insurance rates or prevent ONI from securing insurance coverage in the future.

***ONI's international sales may be limited by complex regulatory, economic, business, insurance and other factors.***

ONI expects that a portion of its revenues will be derived from sales to customers outside the United States. These sales may be less profitable for ONI than domestic sales and may cause ONI to incur substantial expenses without corresponding benefit. As a medical device, the OrthOne system is subject to rigorous and varying regulation in international markets, and sales into new international markets may require compliance with additional burdensome regulations, which could be costly. Because ONI's international distributors fulfill customers' warranty and service needs, ONI does not obtain service maintenance contracts for OrthOne systems sold outside the United States and therefore derives no ongoing service revenue with respect to those systems. In addition, international sales may involve longer sales cycles and greater difficulties in collecting accounts receivable, and any increase in international sales could magnify any adverse consequences arising from currency fluctuations, political or economic instability in foreign markets, or changes in trading policies, reimbursement practices, regulatory requirements, tariffs, or other barriers.

***ONI may have difficulty in identifying and competing for acquisition opportunities.***

ONI's business strategy includes the pursuit of strategic acquisitions to broaden its product line and otherwise improve its business prospects. Although ONI currently does not have any commitments or agreements with respect to any acquisitions, it intends to explore potential acquisitions of strategically complementary product lines, business divisions or companies. ONI may be unable to identify suitable acquisition candidates. In addition, ONI expects to face competition from other companies for acquisition candidates, making it more difficult to acquire suitable companies on favorable terms.



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**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

The forward-looking statements in this proxy statement 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 proxy statement which are not strictly historical statements, including, without limitation, statements regarding management's expectations regarding the ONI merger, the future business of ONI, the staged wind-down of our VBT business, future strategic transactions, if any, possible liquidation and dissolution and future revenues from the sale of our VBT 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 words or comparable words. The factors listed under Risk Factors beginning on page 13, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this proxy statement and presented elsewhere by management from time to time. These 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.



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**SPECIAL MEETING OF SHAREHOLDERS**

This proxy statement and the accompanying form of proxy are being furnished to holders of record of our common stock on July 15, 2005 in connection with the solicitation of proxies by our board of directors for use at a special meeting of shareholders in lieu of an annual meeting, to be held on September 14, 2005, at the JW Marriott Hotel Buckhead Atlanta, 3300 Lenox Road, Atlanta, Georgia, commencing at 9:00 a.m., local time, and at any adjournment or postponement of that meeting.

**Purposes of the Meeting**

At the special meeting, we are asking holders of record of our common stock to consider and vote on the following proposals:

1. The issuance of shares of our common stock to the holders of equity securities of ONI Medical Systems, Inc., a privately held Delaware corporation, pursuant to the terms of a merger agreement with ONI under which ONI will become our wholly owned subsidiary;
2. An amendment to our amended and restated articles of incorporation to increase the authorized number of shares of our common stock from 25,000,000 to 75,000,000;
3. An amendment to our amended and restated articles of incorporation to change our name from Novoste Corporation to ONI Medical Systems, Inc.;
4. The election of two directors to our board of directors;
5. A proposal to adjourn the meeting to permit further solicitation of proxies; and
6. Any other business properly presented at the special meeting or any postponements or adjournments thereof.

Approval of proposal 1 is conditioned on the approval of proposals 2 and 3. Further, if the merger described in proposal 1 is not consummated, then the amendment to authorize additional shares described in proposal 2 and the name change of Novoste described in proposal 3 will not be effected. Therefore, you should consider proposals 1, 2 and 3 together. If any of proposals 1, 2 or 3 is not approved, none of them will be implemented. The merger cannot be completed unless our shareholders approve it. Your vote is very important.

**Recommendation of our Board of Directors**

Our board of directors has unanimously (with one director recused from the matters) determined that our merger with ONI and the related merger agreement are advisable, fair to and in the best interests of our shareholders, has approved the merger agreement, the share issuance and

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the two amendments to our articles of incorporation, and has recommended that you vote FOR the share issuance and the two amendments. Our full board of directors has further unanimously approved, and recommended that you vote FOR, the other proposals described in this proxy statement.

### **Record Date; Shares Entitled to Vote; Quorum Requirement**

Our board of directors has fixed the close of business on July 15, 2005 as the record date for the determination of shareholders entitled to notice of and to vote at the special meeting. Accordingly, only holders of record of shares of our common stock at the close of business on the record date will be entitled to notice of, and to vote at, the special meeting. At the close of business on the record date, there were 16,334,780 shares of our common stock outstanding and entitled to vote, held by approximately 85 record holders.

Each record holder of shares of our common stock on the record date is entitled to cast one vote per share on each proposal properly submitted for the vote of shareholders at the special meeting. Votes may be cast either in person or by properly executed proxy.

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The presence in person or by properly executed proxy of the holders of a majority of the outstanding shares of common stock on the record date is necessary to constitute a quorum for the transaction of business at the special meeting. If a quorum is not present at the meeting, the shareholders present may adjourn the meeting from time to time, without notice, other than by announcement at the meeting, until a quorum is present or represented. Shares represented by proxies that are marked **ABSTAIN** and **broker non-votes** will be counted as present for the purpose of determining the presence or absence of a quorum at the meeting. A **broker non-vote** occurs when a broker holding shares for a beneficial owner does not vote those shares on a particular proposal because the broker does not have discretionary voting power for that particular item and has not received instructions from the beneficial owner.

### **Required Vote; Broker Voting Procedures**

The approval of proposal 1 (the issuance of shares of our common stock pursuant to the merger agreement) requires the affirmative vote of a majority of the total votes cast on the proposal. Only shares that are voted **FOR** or **AGAINST** the proposal will be counted towards the vote requirement. Thus, shares represented at the meeting that are marked **ABSTAIN**, and **broker non-votes**, if any, will not be counted towards the vote requirement. Additionally, if you do not complete and return a proxy card and do not vote in person, there will be no effect on the outcome of the vote on the proposal.

The approval of each of proposals 2 and 3 (the amendments to our articles of incorporation to increase the authorized number of shares of our common stock and to change our name from Novoste Corporation to ONI Medical Systems, Inc.) requires that the number of votes cast by the shareholders at the special meeting in favor of the applicable proposal exceed the number of votes cast against the proposal. Only shares that are voted **FOR** or **AGAINST** the proposal will be counted towards the vote requirement. Thus, shares represented at the meeting that are marked **ABSTAIN**, and **broker non-votes**, if any, will not be counted towards the vote requirement. Additionally, if you do not complete and return a proxy card and do not vote in person, there will be no effect on the outcome of the vote on either proposal.

A plurality of the total votes cast by the holders of our common stock is required to elect each of the two directors (proposal 4). You may vote **FOR** each director nominee or you may **WITHHOLD AUTHORITY** for each director nominee separately. Only shares that are voted in favor of a particular nominee will be counted towards that nominee's achievement of a plurality. Thus, shares represented at the meeting that are not voted for a particular nominee, shares present in person or represented by proxy where the shareholder properly withholds authority to vote for the nominee, and **broker non-votes**, if any, will not be counted towards the nominee's achievement of a plurality.

The approval of proposal 5 (the proposal to adjourn the meeting to permit further solicitation of proxies) requires that the number of votes cast by the shareholders at the special meeting in favor of the proposal exceed the number of votes cast against the proposal. Only shares that are voted **FOR** or **AGAINST** the proposal will be counted towards the vote requirement. Thus, shares represented at the meeting that are marked **ABSTAIN**, and **broker non-votes**, if any, will not be counted towards the vote requirement. Additionally, if you do not complete and return a proxy card and do not attend the special meeting and vote in person, there will be no effect on the outcome of the vote on the proposal.

### **Voting by Directors and Executive Officers**

At the close of business on the record date, our current directors and executive officers beneficially owned and were entitled to vote approximately 8.3% of our common stock outstanding on that date. Each of our current directors and executive officers has entered into a voting agreement with ONI pursuant to which he or she has agreed to vote his or her shares in favor of proposals 1, 2 and 3.

**Voting**

As described below, you may vote by proxy or in person at the special meeting.

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### *Voting in Person*

If you plan to attend the special meeting and wish to vote in person, you will be given a ballot at the meeting. Please note, however, that if your shares are held in street name, which means your shares are held of record by a broker, bank or other nominee, and you wish to vote at the meeting, you must bring to the meeting a proxy from the record holder of the shares authorizing you to vote at the meeting.

### *Voting by Proxy*

Shares of our stock represented by properly executed proxies received at or before the meeting and not revoked will be voted in the manner specified on such proxies. Properly executed proxies that do not contain voting instructions will be voted FOR each of the proposals. If any other matters are properly brought before the special meeting, it is the intention of the persons named in the enclosed proxy card to vote the proxy in accordance with their best judgment. Properly executed proxies marked ABSTAIN, although counted for purposes of determining whether there is a quorum at the meeting, will not be voted.

The enclosed proxy provides that you may vote your shares of common stock FOR the director nominees or you may WITHHOLD AUTHORITY for the nominees, and that you may vote FOR, AGAINST or ABSTAIN from voting with respect to each of the other proposals. The board of directors recommends that you vote FOR each of the two (2) director nominees named in this proxy statement and FOR each of the other proposals.

## **Revocation of Proxies**

A shareholder giving a proxy has the power to revoke it at any time before the vote is taken at the special meeting by:

submitting to our secretary a written instrument revoking the proxy;

submitting a duly executed proxy bearing a later date; or

voting in person at the meeting.

Any written notice of revocation or subsequent proxy should be sent so that it is delivered to us at 4350 International Boulevard, Norcross, Georgia, 30093, Attention: Secretary, or hand-delivered to our secretary at that address, at or before the taking of the vote at the special meeting.

## **Solicitation of Proxies**

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Proxies are being solicited on behalf of our board of directors. We will pay the costs and expenses incurred in connection with the printing and mailing of this proxy statement and the solicitation of the enclosed proxy. In addition to solicitation by mail, our directors, officers and employees may solicit proxies in person or by other means of communication. Our directors, officers and employees will receive no additional compensation for such services, but we may reimburse them for reasonable out-of-pocket expenses in connection with such solicitation. Some of these directors and executive officers may have interests in the proposed merger that differ from yours, as described in Approval of Issuance of Shares in the ONI Merger Interests of Certain Novoste and ONI Persons in the Merger. Brokers, custodians, nominees and fiduciaries will be requested to forward proxy solicitation materials to the beneficial owners of shares held of record by them, and we will reimburse them for the reasonable, out-of-pocket expenses they incur in doing so. We have also retained Morrow & Co., Inc., to aid in the proxy solicitation at an estimated cost of up to \$50,000, plus expenses.

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**Assistance**

If you need assistance in completing your proxy card or have questions regarding the special meeting, please contact:

Novoste Corporation  
4350 International Boulevard  
Norcross, Georgia 30093  
Attention: Daniel G. Hall, Esq., General Counsel  
Phone: (770) 717-0904

Morrow & Co., Inc.  
445 Park Avenue  
New York, New York 10022  
Phone: (800) 654-2468

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**APPROVAL OF ISSUANCE OF SHARES IN THE ONI MERGER**

**(Proposal 1)**

We entered into the merger agreement with ONI on May 18, 2005. ONI is engaged in the development, manufacturing and marketing of dedicated-purpose magnetic resonance imaging systems. You are being asked to consider and vote on the issuance of shares of our common stock to the holders of ONI capital stock, options and warrants pursuant to the merger agreement as consideration for our acquisition of all of ONI's equity securities pursuant to the terms of the merger agreement.

The following is a description of the material aspects of the merger. Although we believe that this description covers the material terms of the merger, the description may not contain all of the information that is important to you. We encourage you to read carefully this entire proxy statement, including the merger agreement attached to this document as *Annex A*, for a more complete understanding of the merger. The following description is subject to, and is qualified in its entirety by reference to, the merger agreement.

**General**

If the merger is completed, we will acquire all of the outstanding equity securities of ONI. As consideration for this acquisition, we will issue shares of our common stock to the holders of ONI's common and Series A preferred stock, and options and warrants to purchase ONI common and Series A preferred stock will be converted into options and warrants to purchase our common stock.

The merger agreement provides that, at the time of the merger, our wholly owned subsidiary, ONIA Acquisition Corp., will merge with and into ONI, whereupon ONI will become our wholly owned subsidiary and the outstanding equity securities of ONI will be converted into the right to receive shares of our common stock. The total number of shares of our common stock to be issued if the merger is completed (including upon exercise of assumed ONI options and warrants) will be determined at the time of closing based on a formula that values us at the value of our net cash assets at closing and values ONI at \$20,000,000 (solely for purposes of this calculation). We anticipate that completion of the merger will result in the current holders of ONI's equity securities owning a majority of our common stock.

**Nasdaq Requirement for Shareholder Approval**

The Nasdaq Stock Market's regulations require that we obtain the approval of our shareholders in connection with any transaction, other than a public offering, involving the sale or issuance by us of common stock (or securities convertible into, or exercisable for, common stock) equal to 20% or more of the common stock, or 20% or more of the voting power of our securities, outstanding before the issuance of the common stock in connection with that transaction. As a result, even though the share issuance is not required to be approved by our shareholders under the terms of the Florida Business Corporations Act, shareholder approval is required under the Nasdaq regulations.

**Potential De-Listing of our Common Stock from the Nasdaq National Market**



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Although our common stock is currently listed on the Nasdaq National Market, a regular trading market for our common stock may not exist or be sustained in the future, in which case you should consider your investment in our common stock illiquid. On April 21, 2005, we received a notice from the Nasdaq Stock Market indicating that we were not in compliance with the Nasdaq Stock Market's requirements for continued listing because, for the previous 30 consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under Nasdaq Marketplace Rule 4450(a)(5). We have until October 18, 2005, to achieve compliance with the minimum requirements for continued listing. If we do not regain compliance with the minimum requirements for continued listing by October 18, 2005, the Nasdaq staff will provide us with written notification that our common stock will be delisted from the Nasdaq National Market.

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In addition, we have been preliminarily informed by Nasdaq staff that our merger with ONI will constitute a change of control transaction, or reverse merger, requiring us to meet Nasdaq's initial listing requirements at the time of closing. These requirements include that our shareholder equity immediately after the merger exceeds \$30 million, and that our common stock satisfies a \$5 per share minimum bid price immediately after closing. We have determined that our shareholder equity immediately after the merger would not satisfy this requirement. As a result, if we are unable to convince Nasdaq staff that the merger does not constitute a reverse merger, we anticipate that our common stock will be unable to remain listed on the Nasdaq National Market after the merger.

If we are unable to retain the listing of our common stock on the Nasdaq National Market, we and ONI intend to attempt to obtain a new listing on the Nasdaq SmallCap Market or American Stock Exchange. To obtain a new listing on the Nasdaq SmallCap Market, we anticipate that our common stock will need to satisfy a \$4 per share minimum bid price requirement immediately after closing. To obtain a new listing on the American Stock Exchange, we anticipate that our common stock will need to satisfy either a \$3 per share minimum bid price requirement or a \$50 million market capitalization requirement immediately after closing. Based on the recent trading price of our common stock, we do not anticipate that our common stock would be able to satisfy either of these requirements unless we completed a reverse share split, in which shares of our common stock would be combined to increase the percentage ownership interest that each share represents. Our board of directors is permitted under Florida law to authorize a reverse share split without the approval of our shareholders, and may consider authorizing such a split to obtain a listing on the Nasdaq SmallCap Market or American Stock Exchange.

If we are unable to retain our listing on the Nasdaq National Market, or obtain a new listing on the Nasdaq SmallCap Market or American Stock Exchange, we may seek to have our stock quoted on the NASD's OTC Bulletin Board, which is an inter-dealer, over-the-counter market that provides significantly less liquidity than the Nasdaq National Market, Nasdaq SmallCap Market or American Stock Exchange. Quotes for stocks included on the OTC Bulletin Board are not as widely listed in the financial sections of newspapers as are those for the Nasdaq National Market. Therefore, prices for securities traded solely on the OTC Bulletin Board may be difficult to obtain and holders of our common stock may be unable to resell their securities at any price. See **Risk Factors** **Risks Related to the Combined Company**.

## **Required Vote**

The approval of the share issuance requires the affirmative vote of a majority of the total votes cast on the proposal. Only shares that are voted **FOR** or **AGAINST** the proposal will be counted towards the vote requirement. Thus, shares represented at the meeting that are marked **ABSTAIN**, and broker non-votes, if any, will not be counted towards the vote requirement. Additionally, if you do not complete and return a proxy card and do not attend the special meeting, there will be no effect on the outcome of the vote on the proposal.

## **Background of the Merger**

For several years, our board of directors had been considering various strategic alternatives in anticipation of the potential impact should drug-eluting stents come to market. In the latter part of 2000, the board considered various opportunities to sell Novoste to strategic buyers, merge with potential partners or acquire other technologies which could leverage our distribution and organizational strengths. Throughout 2001 and 2002, the board considered more than 70 companies after organizing a team composed of several board members and senior managers to screen opportunities. During this period, the board also considered various development projects within Novoste and the likelihood of successful introduction into the market.

Our business and revenues began a steady and rapid decline during 2003 due to, we believe, the approval by the FDA in April 2003 of the market release of drug-eluting stents. In anticipation of this new product technology, our management and board of directors accelerated our

exploration and review of various strategic opportunities and alliances available to us, as well as restructuring activities, shortly after the appointment in October 2002 of Mr. Novak as our President and Chief Executive Officer. In April 2003, we engaged a financial

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adviser to assist us in our review of the strategic alternatives that were available to us and to assist us in our bid for a medical device company that was offered for sale. We were unsuccessful in our bid and we allowed our engagement with this financial adviser to expire. In addition, in anticipation of the impact of drug-eluting stents upon our business, we engaged during 2003 in a restructuring of our organization and significantly reduced our work force over the course of three separate staff reductions. As a result, by the end of 2003, nearly 30% of our workforce had been terminated. Our cost reduction program continued into the first and second quarters of 2004 and included, among other things, the consolidation of all our U.S. operations into a single building. Specifically, at the end of the first quarter of 2004, we implemented a reduction in force, eliminating 84 positions across all functions. This reduction lowered annual operating costs by approximately \$6,000,000. During the first quarter of 2004, approximately 59 of the individuals left Novoste, with the remaining individuals leaving during the second and third quarters. 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, and terminating the 16 employees we had at that time outside the U.S. in accordance with their contracts and the relevant country's employment regulations. We currently have 26 employees, two of whom are employed outside the U.S.

In April 2004, our board of directors, upon the recommendation of management, approved the engagement of Asanté Partners as our investment banking and strategic financial adviser to assist us with our efforts to identify and implement strategic and financial alternatives.

Since April 2004, we and Asanté Partners have identified over 75 businesses as potential candidates for a business combination transaction with us and preliminarily evaluated the merits and likelihood of entering a transaction with each such entity. Novoste and Asanté Partners contacted 67 of those entities to determine their interest in a strategic transaction and held substantial discussions with 10 of those companies.

In September 2004, we and our advisers had engaged in discussions with a European company in the radiation business. The European company had expressed an interest in acquiring our VBT business to complement its other businesses in the United States. The initial proposal submitted by the European company was for it to make a tender offer for all of our outstanding common stock. Before the commencement of its due diligence efforts on our VBT business, the European company had proposed a preliminary per share tender offer price of \$1.05 per share.

We subsequently expanded our search for strategic alternatives outside the cardiology, vascular and radiation therapy fields. On December 14, 2004, Mr. Stephen Shapiro, a member of our board of directors, met with Mr. Novak and advised him of a potential opportunity for us with ONI, a company headquartered in Wilmington, Massachusetts that develops, manufactures and markets dedicated-purpose magnetic resonance imaging systems. Mr. Shapiro is also a director of ONI. Mr. Novak also was informed that Galen Partners IV, LP, to which Mr. Shapiro has provided independent consulting services in the past, is a controlling shareholder of ONI. On December 14, 2004, Mr. Shapiro called Mr. Bruce Wesson, the chairman of the ONI board of directors and the managing director of Galen Partners IV, LP, which at the time owned approximately 38.5% of ONI's common stock on a fully diluted basis. During the call, Mr. Shapiro proposed that the companies explore a potential business combination.

On December 15, 2004, Mr. Novak advised our board of Mr. Shapiro's communication and provided our board with basic information about ONI.

Also on December 15, 2004, Mr. Wesson contacted Mr. Robert Kwolyk and Ms. Darlene Deptula-Hicks, the chief executive officer and chief financial officer of ONI, respectively, to discuss his conversations with Mr. Shapiro and solicited Mr. Kwolyk's and Ms. Deptula-Hicks' views concerning a possible business combination between ONI and Novoste. During the call, Mr. Wesson suggested that ONI engage a financial adviser to assist senior management with their evaluation of any possible transaction. The potential engagement of First Albany Capital Inc. as a financial adviser was discussed at length because First Albany had a prior working relationship with a member of ONI's senior management and because of its substantial experience in similar transactions.



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Later that day, Ms. Deptula-Hicks contacted Jeff Barlow of First Albany to discuss the potential engagement of First Albany to assist ONI management in its analysis of a potential combination with Novoste.

On December 16, 2004, Mr. Kwolyk and Ms. Deptula-Hicks held a conference call with First Albany and ONI's legal counsel, Foley Hoag LLP, to discuss their preliminary assessment of the potential risks and liabilities and strategic and financial benefits of a business combination with Novoste. During this call, the parties discussed potential structures for a transaction and the expected valuations for each company.

At a December 17, 2004 meeting of the Novoste board of directors, Mr. Novak reported to our board, in more detail, regarding the ONI opportunity. Mr. Novak advised the board, among other things, that ONI currently had a commercial product, but was in need of cash for further development and market expansion.

In addition, Mr. James McLaren of Asanté Partners reported to the Novoste board at the December 17, 2004 meeting that during the prior week, he had engaged in conversations with Mr. Shapiro and Mr. Wesson and had confirmed that Galen Partners and ONI management were interested in pursuing a strategic transaction between ONI and Novoste. He advised the board that ONI was a relatively small business, but that it had generated revenues selling its dedicated-purpose magnetic resonance imaging system and that Galen Partners believed the market for the system could be substantial in the United States. He reported further that the founders of ONI were former executives of General Electric Company, who had significant experience in the magnetic resonance imaging industry.

Mr. Novak visited the offices and facilities of ONI on December 20 and 21, 2004. During these visits Mr. Novak met with ONI's management and the individuals at ONI responsible for the development of new products and toured the facilities. Mr. Novak engaged in discussions with ONI's management regarding a potential strategic transaction involving the two companies as well as the interest of ONI's management in such a strategic transaction.

On December 19, 2004, Ms. Deptula-Hicks had discussions with Ernst & Young LLP to discuss a potential engagement to assist ONI with due diligence in connection with a possible transaction with Novoste. Ernst & Young has been ONI's independent auditor since 2002 and also has been our independent auditor since 1992.

The morning of December 23, 2004 Mr. Wesson received a letter from Mr. McLaren of Asanté Partners. The letter confirmed that Novoste believed that a merger with ONI was an attractive opportunity and proposed a transaction whereby Novoste would acquire ONI for a combination of cash and stock.

On December 31, 2004, ONI engaged First Albany to assist ONI senior management in evaluating and negotiating a potential transaction with Novoste.

A regular meeting of the ONI board of directors was held telephonically on January 4, 2005. The board had a lengthy discussion regarding possible venture financing sources for ONI and the potential for a business combination with Novoste. The ONI board discussed the competitive dynamics affecting Novoste's business, the anticipated costs and benefits of merging with a public company, and the economic considerations of pursuing a strategic transaction with Novoste. The ONI board was supportive of ONI senior management having continued discussions with Mr. Novak with the goal of developing a common understanding of the rationale and acceptable terms of a potential transaction. The ONI board then authorized ONI senior management to deliver a letter of intent to Novoste.

On January 5, 2005, ONI delivered a proposed letter of intent to Mr. Novak. ONI proposed a transaction in which ONI would merge with a subsidiary of Novoste in exchange for Novoste common stock. The letter of intent included an exclusivity period and confidentiality provisions.

Our board of directors met on January 7, 2005. Representatives from Hogan & Hartson L.L.P., our legal counsel, and Asanté Partners were present at the meeting. Both the potential ONI transaction and the status of negotiations with the European company were discussed and reviewed by the board and its advisors.

The representatives from Hogan & Hartson L.L.P. discussed with the board the fiduciary duties and responsibilities of our board members with respect to the board's analysis of the potential transactions being discussed.

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Mr. McLaren of Asanté Partners reviewed with the board the proposal being made by ONI. Mr. McLaren advised the board that the proposed transaction would entail Novoste acquiring ONI by a merger pursuant to which ONI would become a wholly owned subsidiary of Novoste and all outstanding ONI equity securities would be converted into the right to receive shares of our common stock. Based upon the preliminary anticipated valuations of ONI and Novoste, Mr. McLaren indicated that it was expected that the shareholders of ONI would own more than a majority of our outstanding common stock immediately after the merger. At the meeting, Mr. Brian Pasdach of Asanté Partners reviewed with our board a summary of the financial data of ONI.

Mr. McLaren reviewed for the board the current proposal from the European company, advising the board that it had not yet conducted due diligence of Novoste and that discussions had not been completed regarding certain elements of the proposal. The board, after review and discussion of the two alternatives, authorized management to proceed with the negotiation and analysis of both proposals.

On January 10, 2005, senior management from ONI and Novoste continued their discussions by telephone concerning the structure of a possible transaction, the time required to complete such a transaction and the need for a Novoste shareholder vote. The parties discussed due diligence items, preparation and filing of a proxy statement and the schedule for completing the audit of ONI's financial statements for 2004.

On January 18, 2005, the board of directors of ONI held a telephonic meeting in order to update the board on recent discussions with senior management of Novoste. The board discussed some of the due diligence being conducted by Novoste and authorized ONI management to provide Novoste with additional financial and market information.

On January 20, 2005, the board of directors of ONI held a telephonic meeting to continue discussions of the terms of a possible transaction with Novoste. The board discussed the aspects of a potential term loan from Novoste as part of the transaction. The board supported senior management's recommendation to continue exploring the possibility of a transaction with Novoste.

On January 24, 2005, representatives from First Albany and Asanté Partners held discussions regarding the timing of a possible transaction and the exclusivity of negotiations between Novoste and ONI. First Albany expressed ONI's concern that the uncertainty and the extended time necessary to solicit a Novoste shareholder vote would make it more difficult to raise capital from other sources if a transaction with Novoste did not receive shareholder approval. First Albany proposed that Novoste provide a bridge loan to address ONI's concerns and the parties discussed potential terms of such a loan. After these discussions, Asanté Partners discussed the possibility and potential terms of a bridge loan to ONI with Novoste senior management and forwarded draft terms to First Albany. Thereafter, ONI senior management drafted a revised letter of intent to be delivered to Novoste.

On January 24, 25, and 26, 2005, management of the European company conducted a due diligence review of our operations at our facility in Norcross, Georgia. The due diligence efforts involved an extensive review of information prepared by us in response to the European company's due diligence requests, along with meetings and discussions with our management and employees.

After these due diligence efforts, discussions continued between our and the European company's financial advisors regarding a potential transaction. Pursuant to these discussions and negotiations, the European company presented a revised proposal to us which provided for a tender offer at a cash price of \$0.60 per share of our common stock. We subsequently provided additional information to the European company to support a higher valuation for our common stock and the European company, after consideration of this information, increased its offer to a price of \$0.75 per share of our common stock.



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On January 26, 2005 the board of directors of ONI held a regularly scheduled meeting. At the meeting, ONI senior management presented the board with an update on three possible equity financing opportunities and an update on the discussions with management of Novoste. The ONI board of directors discussed the relative valuations they expected ONI would receive from each type of financing transaction and discussed the amount, interest rate and security that would be acceptable in connection with a bridge loan from Novoste. The ONI board of directors encouraged ONI senior management to continue to explore potential venture sources as well as a possible transaction with Novoste.

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In January 2005, we filed a Current Report on Form 8-K with the Securities and Exchange Commission to disclose that as part of our review of potential strategic alternatives, we had received inquiries from and had engaged in discussions with several companies potentially interested in a merger or business combination with us. We also disclosed that if a suitable transaction resolving our future on acceptable terms did not become available in the near term, we would need to consider other alternatives, which could include a shut down of our operations, and liquidation and dissolution.

On February 3, 2005, ONI delivered a revised letter of intent to Novoste. During the next week, ONI and Novoste, through their counsel, negotiated the terms of the letter of intent.

On February 11, 2005, the ONI board of directors met to discuss the revised letter of intent. At this meeting, ONI senior management again presented the strategic rationale and the financial implications of the proposed transaction. First Albany gave a presentation concerning the terms of the letter of intent, including the proposal that Novoste would provide ONI with a bridge loan at the time of signing of the merger agreement. After some discussion, the ONI board authorized management to enter into the letter of intent with changes to the provisions concerning the bridge loan and the liabilities associated with Novoste's wind-down plan. After the board meeting, the members of the ONI board not affiliated with Galen Partners met in executive session to discuss negotiations with the holders of ONI's Series A preferred stock in connection with soliciting their consent to a strategic transaction with Novoste and their waiver of certain preemptive rights and preferences. After a lengthy discussion, the group authorized Mr. Douglas Feick, a director of ONI unaffiliated with Galen Partners, to negotiate an exchange ratio with the holders of the Series A preferred stock which would be applicable in a Novoste transaction and which would fairly compensate the holders of ONI's Series A preferred stock for waiving their rights and preferences. Mr. Feick was a partner with Sage Hill Partners, an institutional investor in ONI which as of June 30, 2005 held approximately 193,798 shares, or approximately 2%, of the outstanding ONI Series A preferred stock.

Our board of directors met on February 12, 2005. The board's advisors, Hogan & Hartson L.L.P. and Asanté Partners, were present at the meeting. Mr. Novak advised the board of management's belief that the European company's per share price proposal was inadequate and also expressed concerns regarding the European company's ability to complete a transaction on terms acceptable to us and in a timely manner. In addition, Mr. Novak advised the board that in the course of discussions between Mr. McLaren and the financial advisors to the European company, Mr. McLaren had been informed that any revised offer from the European company would not be substantially higher than the one that had been most recently presented.

Management and Asanté Partners then discussed with the board the proposed ONI transaction. Mr. Novak described and discussed with the board the current proposal from ONI and the anticipated schedule for completing a transaction with ONI. He also reported to the board that a market research organization with whom we have worked in the past had been engaged to conduct a market survey relating to ONI's current dedicated-purpose magnetic resonance imaging system, the OrthOne, and physicians' satisfaction with that system. The market research firm had also assisted ONI in evaluating its follow-on product and assessing the market potential for this new product. In addition, Mr. Novak also explained to the board that Mr. Robert Wood, our then Vice President, Sales and Marketing, would engage in discussions with ONI sales and marketing personnel as part of our due diligence review of ONI. After further discussion of the ONI proposal with our management and the board's advisors, the board authorized Mr. Novak to enter into a letter of intent with ONI and to proceed with further due diligence efforts to determine the merits of the proposed transaction. Promptly after the meeting, we entered into a non-binding letter of intent with ONI regarding the proposed transaction. The letter of intent provided a basic description of the economic terms of the proposed transaction and included both confidentiality and exclusivity provisions. The term of exclusive dealings was initially set to expire upon the earlier of March 6, 2005 or the mutual written agreement of Novoste and ONI not to proceed with negotiations.

On February 14, 15, and 16, 2005, ONI management and its advisors conducted due diligence at our headquarters in Norcross, Georgia. The ONI due diligence team reviewed the information prepared by us in response to ONI's due diligence requests, toured our facilities and met with employees and management.



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Our board of directors met on February 21, 2005. The board discussed the current status of our VBT business and determined that the VBT business was no longer viable. The board authorized management to undertake a staged wind-down of the VBT business. The board determined that this decision was necessary to preserve our cash resources. The board also authorized a further reduction in our workforce. We filed a Current Report on Form 8-K with the SEC to report these developments.

On February 22, 23, and 24, 2005, members of our management and representatives from Hogan & Hartson L.L.P. and Asanté Partners conducted business, financial and accounting due diligence at ONI's corporate headquarters in Wilmington, Massachusetts. The due diligence efforts included a review of, and related discussions with ONI management regarding, ONI's financial statements and business plan, a tour of its manufacturing and administrative facilities and discussions with ONI employees and management. In addition, on February 23, 2005, Mr. Novak and representatives from Asanté Partners attended the American Academy of Orthopedic Surgeons trade show with representatives of ONI's sales team and talked to trade show participants about ONI and its product.

On February 25, 2005 counsel to ONI circulated the first draft of the merger agreement to us. On February 26, 2005, our senior management, counsel and financial advisor held teleconferences in which we discussed a number of business terms in the initial draft of the merger agreement, including, among other things, provisions regarding the payment of break-up fees in certain circumstances, the termination rights and no-shop obligations of the parties and provisions regarding the merger exchange ratios. On February 27, 2005, our counsel orally provided our first response to the draft merger agreement to ONI's counsel, and conveyed our positions on these business terms. During the week of February 28, 2005, our senior management and financial advisor communicated our comments regarding these issues to ONI and its financial advisor, and on March 2, 2005, scheduled a face-to-face meeting among Novoste's and ONI's senior management and respective financial and legal advisors for March 3, 2005.

On March 3, 2005, senior management of Novoste and ONI, along with our respective financial and legal advisors, met in the offices of Foley Hoag LLP in Boston, Massachusetts, to discuss these key business terms and review and negotiate the other terms of the proposed transaction and the related documentation. At this meeting, several of these issues were resolved in principle, and the parties agreed that ONI's counsel would circulate a revised draft of certain sections of the merger agreement based on the resolution of several matters discussed at the meeting, while our counsel would prepare comments on the remaining sections of the agreement.

Our board of directors met on March 4, 2005, to receive an update from our management and our legal and financial advisors on the status of the negotiations with ONI. Mr. Novak discussed with the board various issues currently being negotiated, including the valuation of our assets and liabilities, and the anticipated schedule for completing the proposed transaction with ONI. Mr. Novak discussed various valuation issues with the board and the proposed means to determine the percentage of ownership of the combined company by the current Novoste and ONI shareholders at the close of the transaction. Mr. Novak explained to the board that the ownership allocation would be based upon the amount of net cash assets that Novoste has at the time of closing and the number of orders for, and shipments of, ONI's OrthOne systems.

Also on March 4, 2005, the ONI board of directors met to receive an update on the previous day's negotiations with Novoste. Senior management informed the board that progress had been made in negotiating the terms of a potential business combination and that even though there was no agreement on financial terms, it appeared, based on recent discussions with Mr. Novak, that the ONI valuation would be based on an initial estimate of more than \$20,000,000. Mr. Kwolyk stressed to the board that there were still significant due diligence items under review, including contingent liabilities associated with the wind-down plan of the VBT business. The ONI board then authorized ONI's senior management, financial and legal advisors to negotiate definitive transaction documents to be presented to the board.

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On March 4, 2005, ONI and Novoste executed a letter agreement extending the exclusivity period in the letter of intent until March 16, 2005.

On March 8, 2005, counsel to ONI circulated a revised draft of certain sections of the draft merger agreement, and our counsel provided written comments on the remaining sections of the draft agreement. On March 11, 2005 and March 14, 2005, counsel to ONI responded with revised drafts of the proposed merger agreement. The negotiations surrounding the early drafts of the documents focused on several matters including the mechanism for determining the respective valuations of ONI and Novoste at closing and the resulting merger exchange ratios, the termination and non-solicitation provisions.

At a regular meeting of the ONI board of directors on March 17, 2005, ONI senior management updated the board on the results of ONI's due diligence review of Novoste. There was lengthy discussion regarding the detail of the Novoste wind-down plan for the VBT business and the adjustment mechanisms provided in the proposed merger agreement for the ONI and the Novoste valuations.

On March 23, 2005, counsel for Novoste circulated a revised draft of the merger agreement, an updated wind-down plan for the VBT business and a draft of a preliminary calculation statement under which Novoste and ONI would agree to a mechanism and process for determining our net cash assets at closing, including stipulated dollar values for several of our assets and liabilities.

Senior management of Novoste and ONI, along with our respective financial and legal advisors, met again on April 1, 2005 at the offices of Hogan & Hartson L.L.P. in Washington, D.C. During the course of the discussions and negotiations, various issues were resolved with regard to the merger agreement, including assigning valuation amounts for certain of our identified assets and liabilities, the methodology to be utilized to determine ONI's valuation and the establishment of valuation collars and termination rights for determining the respective ownership interests of the parties at the time of the transaction's closing. After the meeting, a revised draft merger agreement was prepared and distributed to the parties. Over the next four weeks, representatives of the two companies and their respective advisers negotiated the final terms of the merger agreement, our loan to ONI, ONI's promissory note to us, the stock purchase warrant to allow us to acquire shares of ONI's preferred stock and the voting agreement to be signed by our executive officers and directors. The parties also completed their due diligence analyses during this period. On May 5, 2005, attorneys for ONI and Novoste finalized the documentation concerning the respective valuations of the two companies. Following these negotiations, the management of the two companies agreed to recommend the transaction to their respective boards of directors.

The ONI board of directors met on May 11, 2005 and reviewed the proposed transaction. At that meeting, ONI's senior management and financial and legal advisors reviewed the terms and financial implications of the transaction and the exchange ratio, or consideration, to be received by the holders of ONI's common stock, preferred stock, stock purchase warrants and stock options. In addition, management provided their views of the transaction. Following extensive discussion and review of the transaction, the ONI board voted unanimously to approve the merger agreement.

On May 11, 2005, our board of directors met to review and consider the merger agreement, the proposed loan and the other transaction documents. The board received a presentation from Hogan & Hartson L.L.P. regarding the fiduciary duties and responsibilities of the board in connection with the transaction. Hogan & Hartson L.L.P. provided the board with a detailed review of the material terms and conditions of the merger agreement and related transaction documents. The board received a presentation and review of the ONI transaction by our senior management, including a summary of the due diligence performed by us on ONI and its business. Asanté Partners presented the results of its financial and valuation analysis of ONI and the proposed transaction.



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After discussion of the information presented, the board requested that our management arrange for a presentation to the board by ONI's senior management on May 13, 2005. Additionally the board was briefed by our management of the receipt on May 10, 2005 of a proposal by a third party to acquire all of our outstanding common stock by tender offer. Among other things, the proposal required a 30-day due diligence period, a minimum tender condition of 80% of our outstanding common stock in the tender offer and a 90-day exclusivity period. The proposal stated a tender offer price of \$0.90 cash per share. After discussing this development, the board authorized Mr. Novak to respond to the proposal and seek agreement on certain terms more favorable to our shareholders, including an increase in the per share purchase price to \$1.00, a reduction in the minimum tender condition to 50.1%, a break-up fee provision, reduced due diligence and exclusivity periods, and an agreement to commence the tender offer within nine days.

On May 12, 2005, the third party suitor responded to Mr. Novak's request and indicated that it was unwilling to increase its proposed purchase price, reduce the 30-day due diligence period, commence the tender offer by the requested date, or pay a break-up fee if the third party did not commence the tender offer. The third party suitor indicated that it would only commence the tender offer after completion of its due diligence review and the negotiation of a definitive merger agreement.

On May 13, 2005, ONI's senior management made a presentation to our board regarding, among other things, ONI's business, its product, its strategy and business plan, its competitors and the potential market for its product. During this meeting, our board questioned ONI's senior management on these various matters. After completion of the presentation, Mr. Novak updated the board on the third-party tender offer proposal. After discussion and due consideration, the board determined that the tender offer proposal contained too many contingencies and uncertainties to warrant further consideration and that the proposed merger with ONI provided more certainty of completion of a transaction.

On May 16, 2005, our board reconvened to consider the proposed merger agreement and loan to ONI. Mr. Novak updated the board on his recent discussions with various members of ONI management and its board of directors. Asanté Partners presented the final results of its financial and valuation analyses of ONI and the proposed transaction and delivered to the board its oral opinion, subsequently confirmed in writing, that as of that date, the merger consideration to be paid by Novoste in connection with the ONI merger was fair to Novoste from a financial point of view.

The board discussed the information presented by our management and financial advisors. After discussion and due consideration, the board unanimously concluded (with Mr. Shapiro recused from the matters) that the transaction with ONI was in the best interests of Novoste and its shareholders and approved the merger agreement and related agreements, including the loan to ONI in the amount of \$3 million.

On May 17, 2005, significant holders of ONI Series A preferred stock entered into a stockholders agreement with ONI in which they waived certain pre-emptive rights in connection with the merger and agreed to terminate other rights and preferences conditioned upon the closing of a merger with Novoste.

On May 17, 2005, the ONI board of directors executed a unanimous written consent directing the senior management of ONI to seek shareholder approval of the merger agreement and the transactions contemplated therein. On the same day, acting by written consent, the ONI shareholders voted to adopt the merger agreement and the related transactions. The holders of the ONI Series A preferred stock also voted to amend the ONI charter to eliminate provisions relating to the ONI Series A preferred stock dividends, conditioned on the closing of a merger with Novoste.

On May 18, 2005, we and ONI executed the merger agreement and related transaction documents, including the promissory note and stock purchase warrant, and, on May 19, 2005, we transferred to ONI the loan amount of \$3 million.





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**Recommendation of our Board of Directors and Reasons for the Merger**

At a meeting on May 16, 2005, our board of directors unanimously (with one director recused from the matters) determined that the merger and the merger agreement are advisable, fair to and in the best interests of our shareholders, approved the merger agreement, the share issuance and the two amendments to our articles of incorporation, and recommended that you vote in favor of the share issuance and the two amendments.

In reaching its determination to approve the merger agreement and the transactions contemplated thereby and to recommend that our shareholders approve proposals 1, 2 and 3, our board identified several potential benefits for us and our shareholders, including:

the combination with ONI would result in a combined company with a viable business product;

the combination affords our existing shareholders an opportunity for future value that the board believes is currently unavailable given our existing technology;

the potential for growth in ONI's specific business market segment of providing dedicated-purpose, high-field, extremity MRI systems; and

the commitment of ONI to complete the merger on an expedited basis.

Our board consulted with our management, as well as our financial advisor and legal counsel in reaching its decision to approve the merger agreement and the transactions contemplated thereby. The factors that the Novoste board considered include:

the benefits described above;

historical information concerning ONI's and our respective businesses, financial performance, financial condition, operations and management;

our management's view of ONI's and our current business prospects;

our management's view of the financial condition, results of operations and businesses of ONI and Novoste before and after giving effect to the merger and information regarding the merger's potential effect on our shareholder value;

reports from our management and legal, financial and accounting advisors regarding the results of the due diligence investigation of ONI;

presentations by ONI management regarding ONI's business, its technology, its product, its operations and its business plan;

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the opinion of our financial advisor, Asanté Partners, as to the fairness to us, from a financial point of view, of the consideration to be paid in the merger;

our board's belief that the terms of the merger agreement are fair and reasonable;

the terms and conditions of the merger agreement, including the conditions to closing, the termination fee payable to us under certain circumstances, and our ability to terminate the merger agreement for a superior proposal;

that the merger consideration consists of shares of our common stock and does not require the use of cash except for cash paid for fractional shares or upon the exercise of dissenters' rights by ONI's shareholders;

the qualification of the merger as a tax-free transaction for U.S. federal income tax purposes;

the provisions of the merger agreement for determining the composition of the board of directors of the combined company, and the fact that we will initially appoint four of the nine directors on the board and that Mr. Novak will be a nominee of ONI;

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that the merger is the culmination of a search for a strategic transaction that began over a year ago; and

the lack of other future business opportunities for us following the implementation of our wind-down of our VBT business.

Our board of directors also identified and considered various potentially negative factors in its deliberations concerning the merger agreement and the transactions contemplated thereby, including:

the limited operating history of ONI;

the risks related to the immediate and substantial dilution of the equity interests and voting power of our shareholders upon the share issuance and completion of the merger;

the limited public company experience of ONI management;

the risks related to the ability of ONI's current shareholders to significantly influence our business after the share issuance and completion of the merger;

the risk that the combined company may be unable to raise additional capital in the future;

the risk of future competition in ONI's business segment;

the risk that ONI may be unable to successfully implement its business strategy and growth plan; and

certain of the risks described above under "Risk Factors" beginning on page 13.

After due consideration, our board concluded that the potential benefits of the merger to our shareholders outweighed the risks associated with the merger.

Although not exhaustive, this discussion of the information and factors considered by our board comprises the material factors considered. In view of the wide variety of factors considered in connection with the board's evaluation of the merger and related transactions, our board did not quantify or otherwise assign relative weights to the factors described. Rather, our board made its determination based on the totality of the information it considered. Our board cannot assure you that any of the expected results, opportunities or other benefits described in this section will be achieved as a result of the merger.

**OUR BOARD OF DIRECTORS RECOMMENDS A VOTE FOR PROPOSAL 1.**



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### **Opinion of our Financial Advisor**

Our board of directors retained Asanté Partners in April 2004 to act as our investment banking and strategic financial advisor to assist us in our efforts to implement strategic and financial alternatives. In that role, Asanté Partners has acted as our financial advisor in connection with the merger. At a meeting of our board on May 16, 2005 Asanté Partners rendered its oral opinion, subsequently confirmed in writing on May 16, 2005, that as of that date, and subject to and based on the various assumptions made, procedures followed, matters considered and qualifications and limitations of the review set forth therein, the merger consideration was fair to Novoste from a financial point of view.

**The full text of the opinion of Asanté Partners, dated May 16, 2005, which states, among other things, the assumptions made, procedures followed, matters considered and limitations on the review undertaken by Asanté Partners, is attached as *Annex B* to this proxy statement. You should read this opinion carefully and in its entirety. This summary is qualified in its entirety by reference to the full text of the opinion.**

**The Asanté Partners opinion was directed to our board and addressed only the fairness, as of the date of the opinion, from a financial point of view to Novoste of the merger consideration.**

The opinion of Asanté Partners did not address our underlying business decision to proceed with or effect the merger, the merits of the merger as compared to other alternatives potentially available to us or the relative effects of any alternative transaction in which we might engage, nor did it constitute a recommendation to any holder of shares of our common stock as to how such holder should vote with respect to the merger or any other matter. Asanté Partners was not asked to, nor did it, offer any opinion as to any term of the merger agreement or the form of the merger, other than as to the fairness, from a financial point of view, as of the date of the opinion, of the merger consideration to Novoste. In rendering its opinion, Asanté Partners assumed, with our board's consent, that each party to the merger agreement would comply with all the material terms of the merger agreement.

In arriving at its opinion, Asanté Partners, among other things:

reviewed a draft of the merger agreement dated May 9, 2005, including certain exhibits thereto;

reviewed publicly available information relating to Novoste including: the Annual Reports to Shareholders and Annual Reports on Form 10-K of Novoste for the fiscal year ended December 31, 2002 and the fiscal year ended December 31, 2003 and the Annual Report on Form 10-K of Novoste for the fiscal year ended December 31, 2004, Quarterly Reports on Form 10-Q, and current reports on Form 8-K of Novoste;

reviewed certain information prepared by or for ONI management, including, a Private Placement Memorandum, dated August 11, 2002; the audited financial statements of ONI for the three fiscal years ended December 31, 2004; internal unaudited financial statements of ONI for the three months ended March 31, 2005; orders and shipments for ONI products as of March 31, 2005 and a prospect list of potential orders dated May 5, 2005; presentations prepared by ONI management dated February 22, 2005 regarding ONI's business and its 5-year financial projections through fiscal 2009;

reviewed and discussed with representatives of a market research organization an evaluation of the orthopedic MRI imaging equipment market prepared by that organization, dated February 25, 2004;

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discussed with senior management of Novoste and ONI their respective companies historical and current operations, financial condition, strategic objectives and future prospects (including Novoste s proposed wind-down plan);

reviewed a financial due diligence review of ONI prepared by an outside accounting firm on behalf of Novoste and dated March 7, 2005;

reviewed the historical prices and trading volumes of the common stock of Novoste;

visited the headquarters of Novoste and ONI;

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reviewed the pro forma impact of the merger on Novoste;

participated in discussions and negotiations among representatives of Novoste and ONI and their respective legal and financial advisors;

reviewed certain financial data for Novoste and ONI and compared such information with similar information for certain publicly traded companies which it deemed comparable;

reviewed certain mergers and acquisitions of businesses which it deemed comparable;

solicited interest from other parties in merging with or acquiring Novoste or its assets or in licensing products to Novoste; and

performed such other analyses and investigations and considered such other factors as it deemed appropriate.

In preparing its opinion, Asanté Partners assumed and relied on the accuracy and completeness of all information supplied or otherwise made available to it, discussed with or reviewed by or for it, or that was publicly available. Asanté Partners did not assume any responsibility for independently verifying such information or undertake an independent evaluation or appraisal of any of the assets or liabilities of Novoste or ONI, nor did Asanté Partners evaluate the solvency or fair value of Novoste or ONI under any U.S. state, U.S. federal or any other applicable laws relating to bankruptcy, insolvency or similar matters. In addition, Asanté Partners did not assume any obligation to conduct any physical inspection of the properties or facilities of Novoste or ONI. With respect to the financial forecast information furnished to or discussed with Asanté Partners by Novoste or ONI, Asanté Partners assumed that all this information had been reasonably prepared and reflected the best currently available estimates and judgments of the management of Novoste or ONI, as applicable, as to the expected future financial performance of Novoste or ONI, as the case may be. With respect to legal or regulatory matters, Asanté Partners relied on the advice of Novoste's legal and regulatory advisors. Asanté Partners also assumed that the final form of the merger agreement would be substantially similar to the last draft that it reviewed.

We believe that the final form of the merger agreement was not substantially different from the draft reviewed by Asanté Partners.

Asanté Partners' opinion was necessarily based upon market, economic and other conditions as they existed and could be evaluated on, and on the information made available to Asanté Partners as of, the date of its opinion. Asanté Partners has no obligation to update, revise or reaffirm its opinion. Asanté Partners assumed that, in the course of obtaining the necessary consents or approvals (contractual or otherwise) for the proposed merger, no restrictions would be imposed that would have a material adverse effect on the contemplated benefits of the proposed merger.

*Financial Analyses*

At a May 11, 2005 meeting of the Novoste board of directors, and in connection with preparing its opinion for the board, Asanté Partners made a presentation of certain financial analyses of the proposed merger.

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The following is a summary of the material analyses contained in the presentation that was delivered to our board of directors. Some of the summaries of financial analyses include information presented in tabular format. In order to understand fully the financial analyses performed by Asanté Partners, the tables must be read together with the accompanying text of each summary. The tables alone do not constitute a complete description of the financial analyses, including the methodologies and assumptions underlying the analyses, and if viewed in isolation could create a misleading or incomplete view of the financial analyses performed by Asanté Partners.

The fact that any specific analysis has been referred to in the summary below and in this proxy statement is not meant to indicate that such analysis was given more weight than any other analysis; in reaching its conclusion, Asanté Partners arrived at its ultimate opinion based on the results of all analyses undertaken by it



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and assessed as a whole and believes the totality of the factors considered by Asanté Partners in connection with its opinion operated collectively to support its determinations as to the fairness of the merger consideration from a financial point of view. Asanté Partners did not draw, in isolation, conclusions from or with regard to any one factor or method of analysis.

In arriving at its opinion, Asanté Partners made its determination as to the fairness, from a financial point of view, as of the date of the opinion, of the merger consideration to Novoste on the basis of the multiple financial and comparative analyses described below. The following summary is not a complete description of all of the analyses performed and factors considered by Asanté Partners in connection with its opinion, but rather is a summary of the material financial analyses performed and factors considered by Asanté Partners. The preparation of a fairness opinion is a complex process involving subjective judgments and is not necessarily susceptible to partial analysis. With respect to the analysis of publicly traded companies and the analyses of transactions summarized below, such analyses reflect selected companies and transactions, and not necessarily all companies or transactions, that may be considered relevant in evaluating Novoste, ONI or the merger. In addition, no company or transaction used as a comparison is either identical or directly comparable to Novoste, ONI or the merger. These analyses involve complex considerations and judgments concerning financial and operating characteristics and other factors that could affect the public trading or acquisition values of the companies concerned.

The estimates of future performance of Novoste and ONI provided by the management of both Novoste and ONI in or underlying Asanté Partners' analyses are not necessarily indicative of future results or values, which may be significantly more or less favorable than those estimates. In performing its analyses, Asanté Partners considered industry performance, general business and economic conditions and other matters, many of which are beyond our or ONI's control. Estimates of the financial value of companies do not purport to be appraisals or reflect the prices at which companies actually may be sold.

The merger consideration was determined through negotiation between Novoste and ONI and the decision to enter into the merger was solely that of the respective boards of ONI and Novoste. The opinion and financial analyses of Asanté Partners were only one of many factors considered by Novoste's board in its evaluation of the merger and should not be viewed as determinative of the views of Novoste's board or management with respect to the merger or the merger consideration.

Asanté Partners assessed the value of the merger consideration by assessing the value of ONI and the combined company resulting from the merger using several methodologies, including an analysis at various prices, an analysis of future stock prices, a comparable company analysis using valuation multiples from selected publicly traded companies, a comparable transactions analysis using valuation multiples from selected transactions and certain discounted cash flow analyses, each of which is described in more detail in the summaries set forth below. Each of these methodologies was used to generate imputed valuation ranges that were then compared to the merger consideration.

Because the merger consideration is subject to variation based upon the amount of cash held by Novoste and the performance of ONI, Asanté Partners analyzed a range of possible outcomes. Asanté Partners performed certain analyses under each of three possible scenarios that were based on three sets of financial projections:

a case, referred to as the Base Case, which assumes steady revenue growth and cost growth through 2009;

a more positive case, referred to as the Upside Case, which assumes higher revenue growth and higher cost increases; and

a more negative case, referred to as the Downside Case, which assumes lower revenue growth and lower cost increases.

All three of these cases were based upon projections and estimates developed by ONI's and Novoste's management.

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In addition, Asanté Partners generated a range of possible pro forma ownership totals of the combined company by the Novoste shareholders after the merger by assuming our net cash assets would range from \$10 million to \$17 million and ONI's orders and shipments from January 1, 2005 through May 31, 2005 would range from 16 to 44. Asanté Partners viewed the resulting pro forma ownership totals and, based on projections by the management of both Novoste and ONI, selected two totals it deemed most likely to occur—a scenario under which Novoste shareholders would own 38.5% of the resulting company after the merger, referred to as the 38.5% Outcome, and a scenario under which Novoste shareholders would own 45% of the resulting company after the merger, referred to as the 45% Outcome. The 38.5% Outcome and 45% Outcome were then used for certain analyses as described below.

*Analysis at Various Prices.* In order to derive a range of implied equity value multiples for ONI, Asanté Partners performed certain analyses, based on historical information and projections provided by the management of both Novoste and ONI. Assuming share prices of \$0.80 to \$1.00 per share of Novoste common stock, Asanté Partners calculated the implied total enterprise value (on a fully diluted basis) of the merger, assuming the 38.5% Outcome and 16.3 million Novoste shares currently outstanding. Asanté Partners then calculated the ratio of the implied total equity value to (i) 2004 revenues and (ii) estimated 2005 revenues for each of the Base Case, the Upside Case and the Downside Case. The following table presents the results of Asanté Partners' analysis based on prices of \$0.80, \$0.90 and \$1.00 per share (dollar amounts in millions, except for purchase price per share):

	<u>\$0.80 per share</u>	<u>\$0.90 per share</u>	<u>\$1.00 per share</u>
<i>Total Enterprise Value as Multiple of:</i>			
2004 Revenue	2.2x	2.4x	2.7x
2005 Revenue (estimated):			
Base Case	1.2x	1.3x	1.5x
Upside Case	1.0x	1.1x	1.2x
Downside Case	1.8x	2.0x	2.3x

*Present Value of Future Stock Prices.* Asanté Partners also analyzed the level at which the combined company's common stock might trade in the future, after the merger, based on projections by the management of both Novoste and ONI and then-current market conditions. These prices are referred to as the future stock prices, which were then discounted five years to January 1, 2005 at assumed discount rates of 30%, 35% and 40%. These discount rates were based on Asanté Partners' judgment of the risks inherent in ONI's business and the industry in general. Estimated future stock prices were calculated based on (i) 2009 estimated revenue multiples ranging from 1.5x to 2.5x and (ii) 2009 stock price to earnings ratios, or P/E Ratios, ranging from 25.0x to 35.0x. Asanté Partners also assumed 16.3 million Novoste shares currently outstanding and a 35% tax rate. Asanté Partners calculated future stock prices for each of the Base Case, the Upside Case and the Downside Case under the 38.5% Outcome and the 45% Outcome.

Asanté Partners arrived at the following results under the 38.5% Outcome based on a range of multiples of 1.5x to 2.5x for estimated 2009 revenues and 25.0x to 35.0x for estimated 2009 P/E multiples. In the Base Case, this analysis implied an equity value range for the combined company's common stock of between \$0.66 and \$1.63 per share. In the Upside Case, this analysis implied an equity value range for the combined company's common stock of between \$1.06 and \$5.42 per share. In the Downside Case, this analysis implied an equity value range for the resulting company's common stock of between \$0.27 and \$1.27 per share. Asanté Partners compared these results to the price per share of our common stock before the announcement of the merger, which was \$0.86 per share.

For the 45% Outcome, Asanté Partners observed the following results based on a range of multiples of 1.5x to 2.5x for estimated 2009 revenues and 25.0x to 35.0x for estimated 2009 P/E multiples. In the Base Case, this analysis implied an equity value range for the combined company's common stock of between \$0.77 and \$1.92 per share. In the Upside Case, this analysis implied an equity value range for the combined company's common



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stock of between \$1.25 and \$6.33 per share. In the Downside Case, this analysis implied an equity value range for the combined company's common stock of between \$0.32 and \$1.50 per share. Asanté Partners compared these results to the price per share of Novoste's common stock before the announcement of the merger, which was \$0.86 per share.

*Comparable Companies Analysis.* In order to derive a range of implied values for ONI, Asanté Partners reviewed certain financial information of the following publicly traded companies that it deemed comparable to ONI:

CTI Molecular Imaging, Inc.	Hologic, Inc.
Intermagnetics General Corporation	Analogic Corporation
SonoSite, Inc.	Schick Technologies Inc.
Fonar Corporation	Digirad Corporation
Imaging Diagnostic Systems Inc.	Fischer Imaging Corporation
Del Global Technologies Corp.	DOBI Medical International Inc.

Asanté Partners selected this group from companies that are publicly traded medical imaging companies. No company used in the comparable companies analysis was identical to ONI. Asanté Partners performed this analysis to understand the range of multiples of revenue, earnings before interest and taxes, or EBIT, earnings and growth of these comparable companies based upon market prices.

Asanté Partners calculated certain financial ratios of these comparable companies based on the most recent publicly available information and consensus estimates of the Institutional Brokers Estimate System, including the multiples of:

enterprise value (calculated as equity value, plus debt less cash and investments) to the comparable company's revenues for the trailing twelve months ended March 31, 2005 and estimated revenues for the calendar year 2005;

enterprise value to EBIT of the comparable company for the trailing twelve months ended March 31, 2005 and estimated EBIT for the calendar year 2005;

P/E Ratios for the comparable companies using estimated earnings for the calendar years 2005 and 2006; and

The P/E Ratios for the calendar year 2005 for the comparable companies as a multiple of their projected long-term earnings per share growth rate.

In evaluating the multiples for the peer group, Asanté Partners made judgments and assumptions with regard to industry performance, general business, economic, market and financial conditions and other matters, many of which are beyond the control of Novoste and ONI. These other matters include the impact of competition on the business of ONI and the industry generally, industry growth and the absence of any material adverse change in the financial condition and prospects of ONI or in the industry or financial markets in general. Mathematical analysis, such as determining the average or median, is not in itself a meaningful method of using comparable company data.



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Asanté Partners then compared the multiples derived from the selected companies with corresponding multiples for ONI based on the analysis at various prices described above. This analysis indicated the following implied mean and median enterprise value and stock price multiples for the selected companies, as compared to the multiples implied for ONI based on the analysis at various prices:

	<b>Implied Multiples of Comparable Companies</b>	
	<b>Mean</b>	<b>Median</b>
<i>Enterprise Values as Multiple of:</i>		
Revenues		
Trailing Twelve Months ending 3/31/05	2.1x	1.8x
2005 Estimated	2.3x	2.6x
	<b>Implied Multiples for ONI from Analysis at Various Prices <sup>(1)</sup></b>	
	<b>Mean</b>	<b>Median</b>
2004 Revenue	2.4x	2.4x
2005 Revenue		
Base Case	1.3x	1.3x
Upside Case	1.1x	1.1x
Downside Case	2.0x	2.0x

(1) Assumes 38.5% outcome and 16.3 million Novoste shares outstanding. These multiples are the mean and median multiples derived from the analysis at various prices, which observed revenue multiples based on assumed Novoste stock prices ranging from \$0.80 to \$1.00. Please see the section above entitled "Analysis at Various Prices" for more information on the assumptions underlying this analysis.

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*Comparable Transactions Analysis.* Using publicly available information, Asanté Partners reviewed the multiples exhibited and control premiums paid in certain change of control transactions involving companies deemed comparable to ONI by Asanté Partners. The review focused on transactions announced between 2000 and 2004 involving medical equipment manufacturers where the transaction value was approximately \$200 million or less. Asanté Partners identified 15 transactions worth between \$7.1 million and \$200.7 million involving these comparable companies in which transaction multiples were available. Below is a list of these transactions:

<b><u>Date</u></b>	<b><u>Acquiror</u></b>	<b><u>Target</u></b>
June 2004	CTI Molecular Imaging, Inc.	Concorde Microsystems Inc.
May 2004	Intermagnetics General Corporation	MRI Devices Corporation
January 2004	OSI Systems, Inc.	Spacelabs Medical (unit of Instrumentarium Corp.)
December 2003	Intermagnetics General Corporation.	Invivo Corporation
September 2003	Dräger Medical AG & Co. KGaA	Air-Shields (unit of Hillenbrand Industries, Inc.)
April 2003	Invivo Corporation	Medical Data Electronics, Inc. (subsidiary of Viasys Healthcare, Inc.)
January 2003	Ferraris Group Plc	Del Mar Medical Systems LLC
December 2002	Quinton Cardiology Systems, Inc.	Spacelabs Burdick, Inc. (subsidiary of Instrumentarium Corp.)
March 2002	Instrumentarium Corp.	Spacelabs Medical Inc.
December 2001	Respironics, Inc.	Novamatrix Medical Systems Inc.
September 2001	GE Medical Systems (unit of General Electric Co.)	Imatron, Inc.
July 2001	GE Medical Systems (unit of General Electric Co.)	Kretztechnik AG (subsidiary of Medison Co., Ltd.)
October 2000	The Cooper Companies, Inc.	MedaSonics, Inc.
August 2000	GE Medical Systems (unit of General Electric Co.)	ELGEMS Ltd. (50% stake held by Elscint, Ltd.)
August 2000	Hologic, Inc.	Trex Medical Corp. (U.S. assets)

Asanté Partners performed this analysis to understand the range of multiples of revenue of these comparable transactions and estimate the comparable value of ONI.



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The analysis showed that the average multiple of trailing twelve months revenue for the comparable companies exhibited in the change of control transactions listed above as of date of the announcement of the transactions was 1.2x, the median multiple was 0.8x and the high and low multiples were 2.7x and 0.3x, respectively. Asanté Partners utilized these selected multiples after comparing the current market conditions to the market conditions in existence at the time of the comparable transactions, the size and diversification of operations of the comparable companies involved in the transactions and current trends in change of control transactions involving comparable companies. Asanté Partners then compared the implied multiples derived from the selected transactions with the multiples for ONI implied by the analysis at various prices described above:

	Implied Multiples for ONI from Analysis at Various Prices (1)			
	Mean	Median	High	Low
2004 Revenue:	2.4x	2.4x	2.7x	2.2x
2005 Revenue:				
Base Case	1.3x	1.3x	1.5x	1.2x
Upside Case	1.1x	1.1x	1.2x	1.0x
Downside Case	2.0x	2.0x	2.3x	1.8x

- (1) Assumes 38.5% outcome and 16.3 million Novoste shares outstanding. These multiples are derived from the analysis at various prices, which observed revenue multiples based on assumed Novoste stock prices ranging from \$0.80 to \$1.00. Please see the section above entitled "Analysis at Various Prices" for more information on the assumptions underlying this analysis.

*Discounted Cash Flow Methodology – 38.5% Outcome.* Using the 38.5% Outcome, Asanté Partners performed a discounted cash flow analysis of the combined company after the merger based upon each of the Base Case, the Upside Case and the Downside Case.

Utilizing projections provided by the management of both Novoste and ONI, Asanté Partners estimated ONI's annual unlevered free cash flows for the five years ending December 31, 2009. Based in part on current public market valuations, Asanté Partners assumed a range of terminal revenue multiples from 1.5x to 2.5x to calculate the value of ONI's terminal cash flows. Asanté Partners calculated the estimated present value of the annual unlevered free cash flows and terminal cash flows using a range of discount rates from 30% to 40% based on past transactions within the industry and Asanté Partners' judgment of the risk inherent in ONI's business and the industry in general. Based on this analysis, Asanté Partners calculated ONI's equity value from the Base Case to be \$16.0 to \$53.6 million, from the Upside Case to be \$42.5 to \$104.7 million and from the Downside Case to be \$4.0 to \$31.8 million.

Asanté Partners then derived estimates of the combined company's annual unlevered free cash flows for the five years ending December 31, 2009, with pro forma adjustments to reflect the addition of our net cash assets (estimated to be \$12.9 million for purposes of this analysis) to ONI's cash flows in the combined company after the merger. Asanté Partners observed a range of equity values for the combined company ranging from \$28.9 million to \$66.5 million for the Base Case, with resulting pro forma values per share of our common stock of \$0.68 to \$1.57 per share (assuming 42.4 million shares outstanding after the completion of the merger and 16.3 million shares of our common stock outstanding before the merger). These values compare to the price per share of our common stock before the announcement of the merger, which was \$0.86 per share.

*Discounted Cash Flow Methodology – 45% Outcome.* Asanté Partners also performed a similar discounted cash flow analysis of the combined company under the 45% Outcome utilizing the Base Case. Using the Novoste and ONI management projections contained in the Base Case, Asanté Partners estimated ONI's annual unlevered free cash flows for the five years ending December 31, 2009. Based in part on current public market valuations, Asanté Partners assumed a range of terminal revenue multiples from 1.5x to 2.5x to calculate the value of ONI's terminal cash flows. Asanté Partners calculated the estimated present value of the annual unlevered free cash flows and terminal cash flows using a range of

discount rates from 30% to 40% based on past transactions within

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the industry and Asanté Partners' judgment of the risk inherent in ONI's business and the industry in general. Based on this analysis, Asanté Partners calculated ONI's equity value from the Base Case to be \$16.0 to \$53.6 million.

Asanté Partners then derived estimates of the combined company's annual unlevered free cash flows for the five years ending December 31, 2009, with pro forma adjustments to reflect the addition of our net cash assets (estimated to be \$15.0 million for purposes of this analysis) to ONI's cash flows in the combined company after the merger. Asanté Partners observed a range of equity values for the combined company ranging from \$31.0 million to \$68.6 million for the Base Case, with resulting pro forma values per share of our common stock of \$0.85 to \$1.89 per share (assuming 36.3 million shares outstanding after the completion of the merger and 16.3 million shares of our common stock outstanding before the merger). These values compare to the price per share of our common stock before the announcement of the merger, which was \$0.86 per share.

While discounted cash flow analysis is a widely accepted and practiced valuation methodology, it relies on a number of assumptions including growth rates, terminal multiples and discount rates. The valuation derived from the discounted cash flow analysis is not necessarily indicative of ONI's present or future value or results, which could be significantly more or less favorable than such valuation.

*Miscellaneous.* Under the terms of its engagement, Novoste has agreed to pay Asanté Partners for its financial advisory services aggregate fees, including the fee for its fairness opinion, of \$270,000, which have already been paid, and a transaction fee of \$750,000, payable at the closing. Novoste also has agreed to reimburse Asanté Partners for expenses reasonably incurred in performing its services, including fees and expenses of its legal counsel, and to indemnify it and its related persons against liabilities, including liabilities under the federal securities laws, arising out of their engagement.

As described above, the opinion of Asanté Partners was one of many factors taken into consideration by our board in making its determination to approve the merger agreement. The foregoing summary does not purport to be a complete description of the analyses performed by Asanté Partners.

Novoste selected Asanté Partners as its financial advisor because Asanté Partners is a recognized investment banking firm specializing in the healthcare and medical equipment industry, including the segments in which Novoste and ONI operate, with substantial experience in similar transactions. Asanté Partners is continually engaged in the valuation of businesses and their securities in connection with mergers and acquisitions, strategic alliances, competitive bids and private placements. Asanté Partners is currently providing financial advisory services to Novoste and may continue to do so and has received, and may receive, fees for the rendering of such services.

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**TERMS OF THE MERGER AGREEMENT**

The following is a summary of selected provisions of the merger agreement. While we believe this description covers the material terms of the merger agreement, it may not contain all of the information that is important to you and it is qualified in its entirety by reference to the merger agreement. The merger agreement is attached as Annex A to this proxy statement and is considered part of this document. We urge you to carefully read the merger agreement in its entirety for a more complete understanding of the merger.

**Structure of the Transaction**

The merger agreement provides that ONIA Acquisition Corp., our wholly owned subsidiary, will merge with and into ONI, and ONI will be the surviving entity and become our wholly owned subsidiary.

**Merger Consideration**

*Conversion of Securities*

The merger agreement provides that, at the effective time of the merger, each share of ONI common stock and each share of ONI Series A preferred stock, except for dissenting shares, will be converted into the right to receive such number of shares of our common stock as is equal to a specified common stock exchange ratio and Series A exchange ratio, respectively.

The merger agreement further provides that, at the effective time of the merger, the outstanding and unexercised options and warrants to purchase shares of ONI common stock (whether or not vested) will be assumed by us and be converted and become options and warrants to acquire shares of our common stock. Each ONI option and warrant will be exercisable for a number of shares of our common stock equal to the number of shares of ONI common stock issuable under such option or warrant immediately before the merger, multiplied by the common stock exchange ratio. The per share exercise price under each option or warrant will equal the per share exercise price of the ONI common stock under such option or warrant before the merger, divided by the common stock exchange ratio. The outstanding ONI options and warrants will be factored into the calculation of the exchange ratio, even if they are not exercised before the closing.

As further described below, we anticipate that completion of the merger will result in the current holders of ONI's equity securities owning a majority of our common stock.

*Determination of Merger Consideration*

The total number of shares of our common stock issuable to the holders of ONI's capital stock and the holders of ONI options and warrants if the merger is completed will equal:

the total Novoste effective time shares, which is the number of shares of our common stock outstanding at the time of the merger, *plus* the number of shares of our common stock issuable upon exercise of options outstanding at the time of the merger held by our continuing directors or with an exercise price per share of \$2.89 or less;

*multiplied by*

the ONI valuation, which is explained below; and

*divided by*

the Novoste valuation, which is explained below.

As of the record date, we had 16,334,780 shares of our common stock outstanding and 141,000 shares of our common stock issuable upon exercise of options meeting the criteria described above.

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*The ONI Valuation*

The merger agreement provides that the ONI valuation will be \$20,000,000, subject to adjustment depending on the number of orders for OrthOne systems between January 1, 2005 and May 31, 2005 that are accompanied by a payment of at least 10% of the purchase price and that meet certain other standard requirements, and the number of shipments of OrthOne systems for which ONI recognized revenue under GAAP during this same period. Based upon these provisions of the merger agreement, the ONI valuation has now been set at \$20,000,000.

*The Novoste Valuation*

The merger agreement provides that the Novoste valuation will equal the amount of our net cash assets at closing, namely, the difference between the total value of our assets and our liabilities, as set forth on a statement agreed to by the parties at the closing. This statement will set forth our assets and liabilities at closing on a line-by-line basis, and will be in a form and will apply the same methodologies and principles, and stipulating the same dollar values, that have been agreed to by us and ONI. If we and ONI fail to agree on the final statement and the amount of our net cash assets within a specified period of time, each party will have the right to terminate the merger agreement.

The main categories of assets that will be taken into account, to the extent they are applicable, in determining the amount of our net cash assets at the closing are:

our unencumbered cash and cash equivalents;

the principal and interest outstanding under the loan we extended to ONI;

certain of our fixed assets;

our realizable accounts receivable; and

our projected revenue through August 2005.

The main categories of liabilities that will be taken into account, to the extent they are applicable, in determining the amount of our net cash assets at closing are:

operating costs associated with the continued implementation and execution of the wind-down plan after the closing;

costs and liabilities associated with the decommissioning of the AEA line of business and termination of related contractual relationships;

severance and change in control payments;

liabilities associated with pending litigation;

costs associated with termination of operations in foreign countries;

costs associated with the purchase of post-closing insurance for our directors and officers; and

our unpaid transaction expenses.

If the amount of our net cash assets at closing is between \$11,750,000 and \$13,250,000, the Novoste valuation will be fixed at \$12,500,000. If the amount of our net cash assets is less than \$11,750,000, then the Novoste valuation will be the actual amount of the Novoste net cash assets. If the amount of our net cash assets is less than \$10,000,000, ONI will have the right to either terminate the merger agreement or accept a Novoste valuation of \$10,000,000. If the amount of our net cash assets is greater than \$13,250,000 but less than the ONI

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valuation, then the Novoste valuation will be the actual amount of our net cash assets. If the amount of our net cash assets is equal to or greater than the ONI valuation, the Novoste valuation will equal the ONI valuation minus one dollar; however, we will have the right to pay a dividend to our shareholders in the amount, if any, by which the amount of our net cash assets exceeds the ONI valuation.

As of the date of this proxy statement, our board of directors believes that the amount of our net cash assets at the closing will be approximately \$12,500,000. Based on 16,334,780 shares of our common stock outstanding on the record date, and assuming that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000, we currently expect to issue an aggregate of 22,720,304 shares of our common stock and to assume options and warrants to purchase an aggregate of 3,640,944 shares of our common stock if the merger is completed. Based on these assumptions, the current holders of ONI's equity securities would own approximately 58.2% of the issued and outstanding shares of our common stock immediately after the completion of the merger, as well as options and warrants to purchase additional shares. The number of shares issuable to the holders of ONI capital stock, options and warrants, and such holders' combined ownership of our common stock, would increase if the amount of our net cash assets at closing is less than \$11,750,000, and decrease if the amount of our net cash assets at closing is greater than \$13,250,000.

## **Fractional Shares**

No fractional shares of our common stock will be issued at closing in exchange for shares of ONI capital stock. We will pay cash to ONI's shareholders in lieu of fractional shares.

## **Dissenters' and Appraisal Rights**

Our shareholders do not have any dissenters' or appraisal rights in connection with the merger.

Holders of ONI capital stock who demand and perfect appraisal rights in accordance with the Delaware General Corporation Law, and who do not withdraw or lose such appraisal or dissenters' rights before the closing, will not have their shares converted into our common stock. Instead, such holders of ONI capital stock will receive such consideration as may be judicially determined to be due to them with respect to such shares.

If the holders of 10% or more of the outstanding ONI capital stock (determined as if all shares of ONI Series A preferred stock had converted into ONI common stock) demand appraisal rights, we will not be obligated to complete the merger.

## **Effective Time of the Merger**

The merger will become effective upon the filing of a certificate of merger and other appropriate documents with the Secretary of State of the State of Delaware in accordance with the relevant provisions of the Delaware General Corporation Law. The certificate of merger will be filed as soon as practicable on or after the date of closing.



**Board of Directors of the Combined Company**

The merger agreement provides that immediately after the merger, our board of directors will consist of nine directors, five of whom have been designated by ONI and four of whom have been or will be designated by us. One of the five ONI designees is Alfred J. Novak, who is currently our chief executive officer and one of our directors and who will resign from his management position following the merger. One of the four Novoste designees is Stephen I. Shapiro, who is currently a director of both Novoste and ONI.

We have designated Judy Lindstrom, Stephen I. Shapiro and Charles E. Larsen as three of our appointed directors, and we will designate a fourth appointed director before the merger is completed. ONI has designated the following persons as its five appointed directors: Srinj Conjeevaram, David Hable, Robert L. Kwolyk, Alfred J. Novak and Bruce F. Wesson. As a result, since Mr. Novak has been designated by ONI as one of its appointed directors, it is expected that four of the current seven members of our board of directors will remain as directors immediately after the closing of the merger. On the date of closing, in accordance with the merger agreement, we

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will deliver resignations from J. Stephen Holmes, Thomas D. Weldon and William E. Whitmer, and our board will increase the size of the board from seven to nine persons and appoint the four ONI designated appointees and our remaining designated appointee. We and ONI currently anticipate that the board of directors of the combined company will make the following appointments after the merger is completed:

Mr. Hable to serve as Chairman of the Board of Directors;

Ms. Lindstrom to serve as Chairperson of our Corporate Governance and Nominating Committee; and

Mr. Shapiro to serve as Chairman of our Compensation Committee.

We also expect that our fourth designated director appointee, who has not yet been determined, will be appointed by the board to serve as Chairman of our Audit Committee. We intend to seek to appoint an individual who will be independent for purposes of current listing standards of the Nasdaq Stock Market and Section 10A(m)(3) of the Securities Exchange Act of 1934, and who will qualify as an audit committee financial expert, as that term is defined in Item 401(h) of Regulation S-K.

## **Executive Officers of the Combined Company**

The merger agreement provides that on the date of closing, we will deliver to ONI written resignations and releases from each of our executive officers. As a result, Mr. Novak will cease to serve as our President and Chief Executive Officer, Subhash Sarda will cease to serve as our Chief Financial Officer and Daniel Hall will cease to serve as our Vice President, Corporate Secretary and General Counsel. The merger agreement does not provide who will be appointed as our executive officers following the merger. We and ONI currently expect that after the merger is completed, Mr. Kwolyk will serve as our President and Chief Executive Officer, Darlene Deptula-Hicks will serve as our Executive Vice President and Chief Financial Officer, Dr. Peter B. Roemer will serve as our Senior Vice President and Chief Technology Officer and Ron Ramsey will serve as our Vice President of Sales.

## **Representations and Warranties**

The merger agreement contains various representations and warranties of Novoste, ONI and Merger Sub. The representations and warranties are generally reciprocal, such that Novoste and ONI are making substantially similar representations with respect to most matters.

*These representations and warranties have been made solely for the benefit of the parties to the merger agreement and are not intended to be relied on by any other person. You should rely on the disclosure in this proxy statement rather than the representations and warranties in the merger agreement.*

In addition, these representations and warranties are qualified by specific disclosures made to the other parties in connection with the merger agreement, will not survive completion of the merger and cannot be the basis for any claims under the merger agreement after the merger is completed. Moreover, they are subject to the materiality standards contained in the merger agreement, which may differ from what you may regard as material, and are made only as of the date of the merger agreement or such other date as is specified in the merger agreement.

**Conduct of Business Before the Closing of the Merger**

During the period between the signing of the merger agreement and closing, we agreed to conduct our operations solely as in accordance with our wind-down plan. The merger agreement provides that we may also engage in one or more asset sale transactions.

In addition, during this period, we and ONI agreed to refrain from taking specified actions without the prior written consent of the other party. See the merger agreement, which is attached to this proxy statement as Annex A, for further information.

**Indemnification and Insurance of Current Directors and Officers**

The merger agreement provides that after the merger, we and ONI will be obligated to honor our respective obligations under the existing indemnification agreements with our respective directors and executive officers. In addition, the merger agreement provides that, for a period of six years after the merger, our articles of

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incorporation and bylaws, and the certificate of incorporation and bylaws of ONI, may not be amended or otherwise modified in any manner adverse to the rights of any person who served as an officer or director of Novoste or ONI before the merger. During this six-year period, we are obligated to maintain in effect our existing officers and directors liability insurance policies (or substantially similar policies), with respect to claims arising from facts or events that occurred at or before the merger.

We expect to pay the premiums for this insurance coverage before the closing of the merger; if we do not, the premiums will reduce our net cash assets at the closing of the merger.

## **Agreement Not to Solicit Other Offers**

In the merger agreement, subject to the exceptions described below, we agreed that during the term of the agreement, we will not, and we will cause our directors, officers, employees, agents and representatives not to, directly or indirectly:

solicit, initiate, knowingly encourage or facilitate, or furnish non-public information in furtherance of, any inquiries or the making of any proposal with respect to any Novoste competing transaction, which is explained below;

negotiate, explore or otherwise engage in any discussions with any person (other than ONI) with respect to any Novoste competing transaction; or

enter into any agreement, arrangement or understanding requiring us to abandon, terminate or fail to consummate the merger or any other transaction contemplated by the merger agreement.

As used in the merger agreement, a Novoste competing transaction means any of the following:

any recapitalization, merger, consolidation or other business combination or financing involving Novoste or Merger Sub;

the acquisition of any capital stock of Novoste or Merger Sub or 5% or more of the assets of Novoste or any of its subsidiaries;

any acquisition by Novoste or Merger Sub of any material assets or capital stock of any person;

any liquidation of Novoste or Merger Sub; or

any combination of the foregoing.

However, the merger agreement provides that we and our board of directors may furnish information to, or enter into discussions or negotiations with, any person that makes a bona fide written proposal for a Novoste competing transaction which was not invited, initiated, solicited or knowingly encouraged, directly or indirectly, by us, if:

our board of directors determines, after consultation with our financial advisor, that the person has submitted a Novoste competing transaction proposal that has a reasonable likelihood of resulting in a Novoste superior proposal, which is explained below, and determines, after consultation with our outside legal counsel, that such action is required in order for our board of directors to comply with its fiduciary duties under applicable law; and

we promptly informs ONI in writing of the identity of the potential acquirer and the material terms of the proposed transaction.

We also agreed to inform ONI promptly of any related developments, discussions and negotiations with respect to any Novoste competing transaction.

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As used in the merger agreement, a Novoste superior proposal means any bona fide written proposal made by a potential acquirer to enter into a Novoste competing transaction, if as a result:

our shareholders would beneficially own less than 50% of the voting stock, common stock and participating stock of the combined entity; or

the transaction will result in the sale, transfer or other disposition of all or substantially all of our assets;

in each case where our board determines in its good faith judgment, based among other things on the advice of our financial advisor, that the transaction would result in a transaction more favorable to our shareholders from a financial point of view than the merger. In making this determination, our board must take into account all relevant factors, including any material contingencies for the transaction, whether the transaction is reasonably capable of being completed, and any proposed changes to the merger agreement that ONI may propose in response to the transaction. A Novoste competing transaction proposal will not be a Novoste superior proposal unless any required financing is committed or our board reasonably concludes that the financing is likely to be obtained on a timely basis.

In addition, the merger agreement also provides that our board of directors will not:

withdraw or modify, or publicly propose to withdraw or modify, in a manner adverse to ONI, the approval by our board of the merger agreement and the merger, the issuance of Novoste common stock under the merger agreement, the amendment to our articles of incorporation to increase our authorized common stock, and the amendment to our articles of incorporation to change our name;

withdraw or modify, or publicly propose to withdraw or modify, in a manner adverse to ONI, the recommendation by our board to our shareholders to vote in favor of the share issuance proposal, the share increase proposal, and the name change proposal;

approve or recommend, or propose publicly to approve or recommend, any proposal for a Novoste competing transaction;

cause us to enter into, or approve or recommend, or propose publicly to approve or recommend, or execute any letter of intent or any agreement relating to any Novoste competing transaction proposal, or agree to do any of the foregoing; or

submit any Novoste competing transaction proposal at any meeting of our shareholders for purposes of voting upon approval or adoption of the proposal.

However, the merger agreement provides that, before the adoption of the proposals described in this proxy statement, our board of directors may withdraw, amend or modify the approvals and recommendations described above if:

our board determines in good faith, after consultation with our outside legal counsel, that the action is required for our board to comply with its fiduciary obligations to our shareholders; and

our board provides ONI with at least five business days prior notice of its intention to do so.

If the reason that our board of directors intends to withdraw, amend or modify its approvals and recommendations is that it has determined that a Novoste competing transaction proposal is a Novoste superior proposal, then during the five business days following the notice to ONI, we will review any counter-proposal submitted by ONI to determine whether the counter-proposal is at least as favorable to our shareholders as the Novoste superior proposal from a financial point of view. If our board determines that it is, then we and ONI will amend the merger agreement so that the Novoste competing transaction proposal is no longer a Novoste superior transaction proposal.

ONI has agreed to be bound by substantially the same non-solicitation provisions.

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### **Loan to ONI**

Concurrent with the execution of the merger agreement, we extended to ONI an 18-month senior unsecured loan in the principal amount of \$3,000,000, bearing interest at a rate of 8% per year. Principal and interest on the loan will be due in November 2006. Under certain circumstances in which ONI terminates the merger agreement, repayment of the loan will accelerate at the time of termination. The amount of our net cash assets at closing will include the principal and interest outstanding under the loan at such time.

### **Warrant to Purchase ONI Series A Preferred Stock**

In connection with the \$3,000,000 loan, ONI granted to us a warrant to purchase up to 2,325,581 shares of ONI Series A preferred stock (which is convertible into ONI common stock), at an exercise price of \$1.29 per share. We can exercise the warrant either by paying cash or by surrendering the promissory note that evidences the loan. We may not exercise the warrant unless there is an event of default under the promissory note or the merger agreement is terminated. The warrant will expire upon completion of the merger or otherwise in November 2006. Upon termination of the merger agreement under some circumstances, the warrant will automatically terminate. For further discussion, see Termination of the Merger Agreement below.

### **Conditions to Complete the Merger**

The obligations of each party to complete the merger are subject to certain conditions, including:

the approval by our shareholders of the share issuance and the two amendments to our articles of incorporation;

no government orders or restraints seeking to restrain or prohibit the completion of the merger; and

that no more than 10% of the outstanding ONI capital stock (determined as if all shares of ONI Series A preferred stock had converted into ONI common stock) have demanded appraisal rights.

The obligations of ONI to complete the merger are subject to certain conditions, including:

the accuracy of our representations and warranties and performance of covenants and agreements by us;

the resignations of our non-continuing directors and releases and waivers of liability from Messrs. Novak, Hall and Sarda;

the absence of any material adverse effect on us;



the partial waivers by certain of our officers of change of control payments;

ONI's receipt of a legal opinion from counsel to Novoste;

ONI's receipt of a representation letter of Novoste regarding certain tax matters; and

the receipt of all required Novoste consents.

Our obligations to complete the merger are subject to certain conditions, including:

the accuracy of ONI's representations and warranties and performance of covenants and agreements by ONI;

the absence of any material adverse effect on ONI;

our receipt of a legal opinion from counsel to ONI;

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our receipt of all required ONI consents; and

the receipt of certification of ONI regarding ONI not being a U.S. real property holding corporation.

If the law permits, conditions to the completion of the merger may be waived by either ONI or us, as applicable.

**Termination of the Merger Agreement**

The merger agreement may be terminated at any time before the closing of the merger, either before or after the requisite approvals by our shareholders, by mutual written consent of the parties.

In addition, either we or ONI may terminate the merger agreement if:

the merger is not consummated on or before September 30, 2005, but this termination right is not available to a party whose action or failure to act breaches the merger agreement and is a principal cause of the merger not being completed by such date;

a governmental entity shall have issued an order, decree or ruling or taken any other action having the effect of prohibiting the merger;

the share issuance proposal or the share increase proposal is not approved by our shareholders;

the other party materially breaches any representation, warranty or covenant contained in the merger agreement and such breach is not cured within 30 days following written notice of such breach;

we or ONI receives and enters into an agreement with respect to a Novoste superior proposal or ONI superior proposal, as applicable; or

a dispute regarding the amount of our net cash assets at closing arises and cannot be resolved by the parties.

ONI may terminate the agreement if the amount of our net cash assets at closing is less than \$10,000,000, or if any of the following ONI triggering events occurs:

our board of directors or a committee thereof withdraws or modifies in any manner adverse to ONI its recommendation in favor of the approval of the share issuance and the two amendments to our articles of incorporation;

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we failed to include in this proxy statement our board of directors' recommendation in favor of the foregoing proposals, or our board of directors fails to publicly reaffirm that recommendation within 10 days of a request by ONI to do so;

our board of directors or a committee thereof approves or recommends a Novoste competing transaction;

we breach our non-solicitation obligations; or

a third-party tender or exchange offer for our common stock commences and our board of directors fails to send a statement to our shareholders within 10 days recommending rejection of the offer.

We may terminate the agreement if any of the following Novoste triggering events occurs:

the ONI board of directors or a committee thereof withdraws or modifies in any manner adverse to us its recommendation in favor of the adoption of the merger agreement and the merger;

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the ONI board of directors fails to publicly reaffirm that recommendation within 10 days of a request by us to do so;

the ONI board of directors or a committee thereof approves or recommends an ONI competing transaction;

ONI breaches its non-solicitation obligations; or

a third-party tender or exchange offer for securities of ONI commences and ONI's board of directors fails to send a statement to its shareholders within 10 days recommending rejection of the offer.

### **Fees and Expenses**

Generally, each party will pay its own fees and expenses incurred in connection with the merger agreement. However, the termination of the merger agreement under certain circumstances will result in either a termination of the ONI warrant or in an obligation to pay a fee.

The ONI warrant will automatically terminate if:

either we or ONI terminates the merger agreement, because either the share issuance proposal or the share increase proposal is not approved by our shareholders, and, within 12 months, we enter into an agreement to engage in a Novoste competing transaction;

ONI terminates the merger agreement because an ONI trigger event occurs;

ONI terminates the merger agreement because we materially breach a representation, warranty or covenant in the merger agreement and the breach is not cured within 30 days after written notice of the breach; or

we terminate the merger agreement to enter into an agreement with respect to a Novoste superior proposal.

ONI will be obligated to pay us a termination fee of \$500,000 if:

we terminate the merger agreement because a Novoste triggering event occurs; or

ONI terminates the merger agreement to enter into an agreement with respect to an ONI superior proposal.

If we terminate the merger agreement because ONI materially breaches a representation, warranty or covenant in the merger agreement and the breach is not cured within 30 days after written notice of the breach, ONI will be obligated to pay us the fees and expenses we incurred in connection with the merger agreement, up to a maximum of \$500,000.

**ONI Board and Shareholder Approval**

The board of directors of ONI has adopted a resolution approving the merger agreement and the merger and declaring them advisable. When ONI signed the merger agreement, certain shareholders of ONI representing a majority of the voting power of ONI's capital stock signed written consents approving and adopting the merger agreement and the merger. In these written consents, the shareholders also waived their rights to dissent from the merger and seek appraisal of the shares of ONI capital stock they own.

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**RELATED AGREEMENTS**

**Novoste Voting Agreements**

Concurrent with the execution of the merger agreement, our directors and executive officers entered into voting agreements (including irrevocable proxies) in which, among other things, each of them agreed to vote in favor of the share issuance and the two amendments to our articles of incorporation.

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER**

We expect the merger to qualify as a tax-free reorganization under Section 368 of the Internal Revenue Code. We expect that there will be no material federal income tax consequences from the merger for our continuing shareholders.

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**INTERESTS OF CERTAIN NOVOSTE AND ONI PERSONS IN THE MERGER**

**Change in Control Payments**

In May 2003, we entered into amended and restated termination agreements with the following executive officers: Alfred J. Novak, Andrew M. Green, Daniel G. Hall, Adam G. Lowe, Subhash C. Sarda, Susan D. Smith, Robert N. Wood, Jr., Gordon Snyder and Jeanne Marie Leahy. Each of the termination agreements provides for benefits in the event of a termination of the employment of the applicable executive officer after a change in control of Novoste. Each of the termination agreements had an initial term from the date of execution of the termination agreements through December 31, 2003. Each of the termination agreements is automatically extended each January 1 for a one-year term, unless notice not to extend the agreement is given not later than 12 months before such January 1. Each of the agreements has been extended through December 31, 2005. If a change in control (as defined in the termination agreement) occurs during the term, each 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.

Under the terms of each termination agreement, upon a change in control of Novoste and the subsequent termination of the employment of the applicable executive officer by us without cause or by the employee for good reason, the executive officer will receive benefits including 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, we are obligated to make whole the executive officer with respect to such excise tax.

On May 18, 2005, we entered into amendments to the termination agreements with each of these executive officers. Each amendment provides that in the case of a change in control of Novoste involving ONI or certain other parties, but only in such cases, the severance payment payable to the applicable executive officer currently equal to three times annual salary and bonus will be reduced as follows:

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to 1.75 times annualized salary (as calculated pursuant to the terms of the amended and restated termination agreements and the termination agreement amendments) for executive officers other than Alfred J. Novak, our President and Chief Executive Officer; and

to two times salary and performance bonus (as calculated pursuant to the terms of his amended and restated termination agreement and his termination agreement amendment) for Mr. Novak.

Our board of directors has determined that completion of the merger will constitute a change in control under the termination agreements, as amended. The employment of Ms. Smith, Ms. Leahy and Messrs. Green, Lowe, Wood and Snyder has been terminated. In addition, under the terms of the merger agreement, Messrs. Novak, Hall and Sarda will be resigning their employment positions as of the closing. As a result, the completion



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of the merger will result in change in control payments being due to each of these executive officers, in the following amounts:

<u>Name</u>	<b>Termination Payment</b>
	<b>Due After Merger</b>
Alfred J. Novak	\$ 989,912
Daniel G. Hall	\$ 341,250
Subhash C. Sarda	\$ 315,000
Andrew M. Green	\$ 131,250
Jeanne Marie Leahy	\$ 75,000
Adam G. Lowe	\$ 136,500
Susan D. Smith	\$ 123,750
Gordon Snyder	\$ 84,375
Robert N. Wood, Jr.	\$ 176,250

**Stock Option Waivers**

In connection with the merger agreement, each of Messrs. Novak, Hall and Sarda executed a waiver providing that all of his Novoste stock options will terminate automatically upon the completion of the merger.

**Board Compensation**

As discussed in the section entitled "Approval of Issuance of Shares in the ONI Merger - Terms of the Merger Agreement - Board of Directors of the Combined Company," Ms. Lindstrom and Messrs. Novak, Larsen and Shapiro will remain as our directors after the completion of the merger. We and ONI anticipate that after the completion of the merger, Mr. Novak and our additional board appointee will each receive a restricted grant of 40,000 shares of our common stock, and Ms. Lindstrom and Messrs. Larsen and Shapiro, as well as ONI's four additional appointees to the combined company board, will each receive a restricted grant of 20,000 shares of our common stock. It is currently anticipated that non-employee directors of the combined company will continue to receive annual restricted grants of not less than 20,000 shares of our common stock as compensation for board service.

In addition, we and ONI anticipate that non-employee members of the combined company board will receive the following compensation:

<b>Annual Retainer:</b>	
Chairman of the board	\$ 144,000
Chairman of the audit committee	\$ 20,000
<b>Board Meeting Attendance Fees (in-person):</b>	
Non-employee directors	\$ 2,000
Non-employee directors attending by telephone	\$ 500
Telephonic Board Meeting Attendance Fees	\$ 1,000
<b>Committee Meeting Attendance Fees:</b>	
Chair	\$ 1,500
Committee member	\$ 1,000

Telephonic Committee Meeting Attendance Fees:	
Chair	\$ 1,000
Committee member	\$ 500

**Agreement with David Hable**

We and ONI have agreed to retain Mr. Hable as the Chairman of our board of directors after the merger. If Mr. Hable remains Chairman of the board of directors, we expect that he will receive approximately \$12,000 per month as a retainer. Mr. Hable is expected to spend up to three days per week working with the combined company in his capacity as Chairman.

**Table of Contents****PRO FORMA SECURITY OWNERSHIP OF NOVOSTE AFTER THE MERGER**

The following table provides information, after giving pro forma effect to the merger, with respect to the anticipated beneficial ownership of our common stock by:

each person expected to be a director or executive officer of the combined company;

all such directors and executive officers as a group; and

each person expected to be the beneficial owner of more than five percent of our common stock anticipated to be outstanding after the merger (based on such person's current beneficial ownership of Novoste or ONI equity securities).

The information in this table assumes that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000. The exchange ratios at which holders of ONI equity securities will have their ONI equity securities converted into Novoste equity securities will vary from the ratios assumed in this table if the amount of our net cash assets at closing is greater than \$13,250,000 or less than \$11,750,000. For a further description of how these exchange ratios will be determined at closing, see Approval of Issuance of Shares in the ONI Merger Terms of the Merger Agreement Merger Consideration.

Beneficial ownership is determined under the rules of the Securities and Exchange Commission and generally includes voting or dispositive power over the securities. The percentage of beneficial ownership is based on the assumption that there will be 39,255,084 shares of our common stock outstanding after the merger, representing the sum of 16,334,780 shares of Novoste common stock currently outstanding as of the record date, 15,855,278 shares of Novoste common stock expected to be issued to the holders of ONI's outstanding series A preferred stock, 6,865,026 shares of Novoste common stock expected to be issued to the holders of ONI's outstanding common stock, and 200,000 restricted shares of Novoste common stock expected to be granted to the non-employee directors of the combined company after completion of the merger. Shares of our common stock and ONI's common stock subject to options and warrants that are currently exercisable or exercisable within 60 days of July 15, 2005, the record date, are considered outstanding and beneficially owned by the person holding the options and warrants for the purpose of computing the pro forma percentage ownership of that person but are not treated as outstanding for the purpose of computing the pro forma percentage ownership of any other person.

Name	Shares	Options and Warrants	Total Beneficial Ownership	Percentage
<i>Principal shareholders of the combined company</i>				
Galen Partners IV, LP and affiliated entities (1)	12,161,806	34,731	12,196,537	31.0%
Steel Partners II, L.P. and affiliated entities (2)	2,433,207		2,433,207	6.2%
<i>Directors and executive officers of the combined company</i>				
Srini Conjeevaram (3) (4)	12,161,806	34,731	12,196,537	31.0%
Bruce F. Wesson (4) (5)	12,161,806	34,731	12,196,537	31.0%
Robert L. Kwolyk	868,286	239,241	1,107,527	2.8%
Peter B. Roemer	868,286	200,655	1,068,941	2.7%
Charles E. Larsen (4)	331,161	35,000	366,161	*
Darlene M. Deptula-Hicks		212,232	212,232	*
Ron D. Ramsey		92,617	92,617	*

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Stephen I. Shapiro (4)	24,213	52,365	76,578	*
Judy Lindstrom (4)	20,000	35,000	55,000	*
David Hable (4)	20,000	26,048	46,048	*
Alfred J. Novak (6)	40,000		40,000	*
Additional Novoste board appointee (7)	40,000		40,000	*
All directors and executive officers as a group (12 persons)	14,373,752	927,889	15,301,641	38.1%

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- (1) Represents shares issuable upon conversion of 6,143,646 shares of ONI Series A preferred stock held by Galen Partners IV, LP, 846,749 shares held by Galen Partners International IV, LP, and 2,962 shares held by Galen Employee Fund IV, LP and shares issuable upon exercise of stock options to purchase 30,000 shares of ONI common stock held by Galen Investment Advisory Group. Also includes 20,000 restricted shares of our common stock to be granted to each of Mr. Conjeevaram and Mr. Wesson, in their capacities as non-employee directors of the combined company, after completion of the merger. The address of Galen Partners IV, LP is 610 Fifth Avenue, 5<sup>th</sup> Floor, New York, New York 10020.
- (2) Information obtained from a Schedule 13D/A filed with the SEC by Steel Partners II, L.P. and Steel Partners, L.L.C. on April 15, 2005. 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 Steel Partners, L.L.C., Warren G. Lichtenstein may be deemed to beneficially own all of these shares. The address of Steel Partners 590 Madison Avenue, 32nd Floor, New York, New York 10022.
- (3) Includes 12,196,537 shares beneficially owned by Galen Partners IV, LP, as described in note 1. As general partner of Galen Partners IV, LP, Galen Partners International IV, LP, and Galen Employee Fund IV, LP, Mr. Conjeevaram may be deemed to share voting and investment power for the shares held by the foregoing funds. Mr. Conjeevaram disclaims beneficial ownership of the shares held by funds affiliated with Galen Partners IV, LP except to the extent of his pecuniary interest therein.
- (4) Includes 20,000 restricted shares of Novoste common stock to be granted to the director after completion of the merger.
- (5) Includes 12,196,537 shares beneficially owned by Galen Partners IV, LP, as described in note 1. As managing director of Galen Partners IV, LP, Galen Partners International IV, LP, and Galen Employee Fund IV, LP, Mr. Wesson may be deemed to share voting and investment power for the shares held by the foregoing funds. Mr. Wesson disclaims beneficial ownership of the shares held by funds affiliated with Galen Partners IV, LP except to the extent of his pecuniary interest therein.
- (6) Includes 40,000 restricted shares of our common stock to be granted to Mr. Novak after completion of the merger, and reflects the cancellation of options to purchase 394,350 shares of our common stock that will automatically terminate at the closing of the merger.
- (7) Additional board member to be designated by us before the merger is completed. Includes 40,000 restricted shares of Novoste common stock to be granted to this board member after completion of the merger.

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### **BUSINESS OF NOVOSTE**

#### **Overview**

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 VBT business, our sales of those 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 a result, on February 22, 2005, we announced that our board of directors had determined that our VBT business, which is our only business line, was no longer viable and, as a result, the board had 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 would reduce our U.S. workforce in the first quarter of 2005 by 52 employees, from 81 employees. Additionally, we notified all 16 of our employees outside the U.S. that they would be terminated in accordance with their contracts and the relevant country's employment regulations in an effort to further reduce our costs. We currently have 26 employees, 2 of whom are employed outside the U.S. Our board determined that this decision was necessary to preserve our cash resources and arose as a result of the continuing decline in revenue for our VBT 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 VBT business. As part of our ongoing review of potential options, we retained an investment banking and strategic advisor, Asanté Partners, in April 2004, to assist us in our efforts to identify and implement strategic and financial alternatives. As discussed elsewhere in this proxy statement, on May 18, 2005, we entered into the merger agreement with ONI. If the merger is not completed, we will need to consider other alternatives, which could include liquidation and dissolution.

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, if 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 the 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, by expenses incurred in pursuing the merger with ONI and other strategic alternatives, and by the ultimate amounts paid in settlement of our liabilities. Before 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 those 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**

We 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

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in the European Union in January 1999. On November 3, 2000, we received U.S. marketing approval from the 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 had determined that our VBT business is no longer viable, and as a result, the board had 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, 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. Before 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.

## **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, or PTCA, procedure.

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



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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. 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, or 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



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into the vessel, reducing the incidence of restenosis by over half, as compared to a bare metal stent, or BMS. Johnson & Johnson received FDA approval for its Cypher DES in April 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 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 also believe that the overall number of DES procedures will continue to grow 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 elsewhere in this proxy statement, we announced on February 22, 2005 that our board of directors had determined that our VBT business is no longer viable and, as a result, the board had authorized a staged wind-down of our business. Our board of directors determined that this decision was 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 VBT business. As part of our ongoing review of potential options, we retained an investment banking and strategic advisor, Asanté Partners, in April 2004, to assist us in our efforts to identify and implement strategic and financial alternatives. As discussed elsewhere in this proxy statement, on May 18, 2005, we entered into the merger agreement with ONI. If the merger is not completed, 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 except as required by regulatory agencies.

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 our 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, or 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.

All post-approval studies that were initiated with the Beta-Cath System have been completed, with data reported to the FDA, and all trial sites are closed. The MOBILE Trial is considered completed at this time, as all trial sites have been closed and the Final Report has been issued to the

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 the FDA and to the trial sites by July 31, 2005. Therefore, in connection with the wind-down of our VBT business operations, all of our clinical trial commitments, in the U.S. and outside the U.S., should be met in the third quarter of 2005.

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### **Sales and Marketing**

In connection with the wind-down of our VBT business, we have substantially ceased our sales and marketing activities as part of the staged wind-down of the business and are meeting customer product requests based on demand for VBT product.

### **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, before 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](#) below. 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, or 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 us with radioactive sealed Strontium-90 seed trains. During each calendar year under the four-year contract, we guaranteed minimum annual payments to Bebig in varying amounts. All product purchases are credited against the annual guaranteed payment. If we 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 was paid in the first quarter of 2005 and was fully accrued as of December 31, 2004. Our obligation of \$250,000 to reimburse Bebig for expenses associated with decommissioning the production line has been fulfilled.

On October 14, 1999, we signed a development and manufacturing supply agreement with AEA Technologies WSA GmbH 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 us 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. We paid the cost of this production line as construction progressed. Depreciation of the production line began when the equipment was placed into service, in October 2002. In addition, the agreement provides for joint ownership of all intellectual property arising from the development work and that AEA may manufacture vascular brachytherapy sources only for us. Annual minimum purchase commitments and pricing guidelines were established extending to 2006. During 2004, we did not reach the minimum purchase commitment level for product and incurred an expense in cost of sales of \$695,000 for this shortfall. On March 9, 2005, we provided the required 18-month notification to terminate the contract in September 2006 and accrued the balance of the estimated minimum payment obligations, recording a total liability of \$1,324,000 as of March 31, 2005. At the termination of the agreement, we are 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. Both of these estimated amounts are subject to negotiation and settlement with AEA.

**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, no. 5,899,882 on

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May 4, 1999, no. 6,013,020 on January 11, 2000, no. 6,261,219 on July 17, 2001 and no. 6,306,074 on October 23, 2001, all of which relate to both or either the Beta-Cath System with an over-the-wire catheter or the Beta-Cath System with a rapid exchange catheter. We also have several additional United States applications pending covering aspects of our Beta-Cath System. With respect to the above identified United States patents and our other pending United States patent applications, we have filed 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, a California limited liability corporation, filed suit against us and one of our customers, Rush-Presbyterian St. Luke's Medical Center in the United States District Court for 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 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 patents 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





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Beta-Cath System. The term of the agreement runs through the later of the date the last patent covered by the agreement expires or 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 terminates the agreement as a result of our failure to pay royalties or any other breach of our obligations under the 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 will 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, and generally require pre-market clearance or pre-market approval before 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 before its commercialization, which occurred in November 2000.

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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

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with the use of the device. Device manufacturers are required to register their establishments and list their devices with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and those state agencies. The Food, Drug, and Cosmetic Act requires device manufacturers to comply with good manufacturing practices regulations, called the quality systems regulations, or 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, or 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 before 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.

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### *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 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 that our board of directors had determined that our VBT business, which is our only business line, was no longer viable and, as a result, the board had authorized a staged wind-down of our business. On that date, we notified all 16 of our employees outside the U.S. that they would be terminated in accordance with their contracts and the relevant country's employment regulations in an effort to further reduce our costs. 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.

On February 22, 2005, we announced that our board of directors had determined that our VBT business, which is our only business line, was no longer viable and, as a result, the board had 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 would reduce our U.S. workforce in the first quarter of 2005 by 52 employees, from 81 employees. Additionally, we notified all 16 of our employees outside the U.S. that they would be terminated in accordance with their contracts and the relevant country's employment regulations in an effort to further reduce our costs.

We currently have 26 employees, two of whom are employed outside the U.S.



**Table of Contents****MARKET FOR NOVOSTE S COMMON STOCK**

Our common stock has been traded on the Nasdaq National Market (Nasdaq symbol: NOVST) since May 1996. The number of record holders of our common stock on the record date was 85, excluding beneficial owners of shares that are registered in nominee or street name. We have not paid any cash dividends since our inception.

The range of high and low closing sale prices for our common stock for each quarterly period listed below is as follows:

<b><u>Quarter Ended</u></b>	<b><u>High</u></b>	<b><u>Low</u></b>
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
Year Ended December 31, 2005		
March 31, 2005	\$ 1.61	\$ 0.85
June 30, 2005	\$ 0.98	\$ 0.82
September 30, 2005 (through August 3, 2005)	\$ 0.98	\$ 0.87

On August 3, 2005, the last reported sale price for our common stock was \$0.92.

On April 21, 2005, we received a notice from the Nasdaq Stock Market indicating that we were not in compliance with the Nasdaq Stock Market's requirements for continued listing because, for the previous 30 consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under Nasdaq Marketplace Rule 4450(a)(5). We have until October 18, 2005, to achieve compliance with the minimum requirements for continued listing. If we do not regain compliance with the minimum requirements for continued listing by October 18, 2005, the Nasdaq staff will provide us with written notification that our common stock will be delisted from the Nasdaq National Market.

In addition, we have been preliminarily informed by Nasdaq staff that our merger with ONI will constitute a change of control transaction, or reverse merger, requiring us to meet Nasdaq's initial listing requirements at the time of closing. These requirements include that our shareholder equity immediately after the merger exceeds \$30 million, and that our common stock satisfies a \$5 per share minimum bid price immediately after closing. We have determined that our shareholder equity immediately after the merger would not satisfy this requirement. As a result, if we are unable to convince Nasdaq staff that the merger does not constitute a reverse merger, we anticipate that our common stock will be unable to remain listed on the Nasdaq National Market after the merger.

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If we are unable to retain the listing of our common stock on the Nasdaq National Market, we and ONI intend to attempt to obtain a new listing on the Nasdaq SmallCap Market or American Stock Exchange. If we are unsuccessful, we may seek to have our stock quoted on the NASD's OTC Bulletin Board, which is an inter-dealer, over-the-counter market that provides significantly less liquidity than the Nasdaq National Market, Nasdaq SmallCap Market or American Stock Exchange. For a further description, see [Approval of Issuance of Shares in the ONI Merger](#), [Continued Listing of our Common Stock on Nasdaq](#) and [Risk Factors](#) [Risks Related to the Combined Company](#).

**Table of Contents****SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA OF NOVOSTE**

The selected consolidated 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 proxy statement. The selected consolidated financial data shown below for the fiscal quarters ended March 31, 2005 and 2004, and as of March 31, 2005, have been taken or derived from our unaudited financial statements included in this proxy statement. In the opinion of management, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the results of the interim periods. Operating results for the three months ended March 31, 2005 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2005. The selected consolidated financial data shown 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 proxy statement. The selected consolidated financial data shown below should be read in conjunction with the consolidated financial statements and related notes of Novoste and with Novoste Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this proxy statement.

	Three Months Ended		Year Ended December 31				
	March 31						
	2005 (1)	2004	2004	2003	2002	2001	2000
(In thousands, except per share amounts)							
<b>Consolidated Statement of Operations Data:</b>							
Net sales	\$ 3,413	\$ 7,025	\$ 23,268	\$ 62,901	\$ 69,030	\$ 69,908	\$ 6,530
Costs and expenses:							
Cost of sales	4,118	3,953	16,111	24,315	27,313	19,164	4,258
Impairment and related charges			9,349		6,900		
Research and development	434	2,475	4,633	11,986	13,300	12,756	17,119
Sales and marketing	2,702	3,489	12,558	19,485	26,875	35,868	15,651
General and administrative	2,878	1,800	8,036	8,237	8,335	9,324	6,321
Loss from operations	(6,719)	(4,692)	(27,419)	(1,122)	(13,693)	(7,204)	(36,819)
Other income	165	78	498	254	642	2,095	3,746
Net loss	\$ (6,554)	\$ (4,614)	\$ (26,921)	\$ (868)	\$ (13,051)	\$ (5,109)	\$ (33,073)
Basic and diluted net loss per share	\$ (0.40)	\$ (0.28)	\$ (1.65)	\$ (0.05)	\$ (0.80)	\$ (0.32)	\$ (2.13)
Weighted average shares outstanding	16,335	16,331	16,333	16,313	16,268	16,152	15,157

	At	At December 31				
	March 31,	2004	2003	2002	2001	2000
	2005 (1)					
(In thousands)						
<b>Consolidated Balance Sheet Data:</b>						
Working capital	\$ 19,618	\$ 25,753	\$ 39,364	\$ 30,496	\$ 40,482	\$ 53,742
Total assets	27,043	33,702	61,407	67,520	82,911	77,073
Long-term liabilities				5	203	401
Accumulated deficit	(168,777)	(162,223)	(135,302)	(134,434)	(121,384)	(116,275)
Total shareholders' equity	19,806	26,454	53,244	52,765	64,728	67,042



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- (1) On February 22, 2005, we announced that our board of directors had determined that our vascular brachytherapy business, which is our only business line, is no longer viable and, as a result, had authorized a staged wind-down of the business. As described in the notes to our financial statements, assets have been stated at estimated net realizable and accruals have been recorded to reflect the business assumptions of the wind-down in accordance with FAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*.

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**NOVOSTE MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

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, and to 200 at June 30, 2005.

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, we announced a reduction in force to take an additional 87 positions out of the work force. On April 22, 2004, we concluded an asset purchase agreement with Guidant Corporation, pursuant to which we 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, we became the sole provider of coronary brachytherapy products (see Notes 7 and 13 to consolidated financial statements). As noted below, we 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, we 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, we have 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, we 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.

The net loss for the quarter ended March 31, 2005 was \$6,554,000 on revenues of \$3,413,000. The loss in the quarter includes a charge of \$2,401,000 for employment termination costs, as well as other wind-down related costs, and \$1,324,000 to recognize the estimated remaining minimum purchase commitments due to a supplier. Offsetting these charges is a favorable effect on cost of sales from the elimination of depreciation and amortization expense due to reductions and write-offs of capitalized assets resulting from impairments and other write-downs recorded in the last 6 months. We expect continued losses as operations wind down and revenues continue to decline while we review potential options.



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On February 22, 2005, we announced that our board of directors had determined that our VBT business, which is our only business line, is no longer viable, and as a result, the board had authorized a staged wind-down of our business. Following the announcement, we commenced the first stage of the wind-down and terminated employment of approximately 50 employees. Further reductions in employees and other cost reduction measures are being implemented on a regular basis.

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 VBT business. As part of our ongoing review of potential options, we retained an investment banking and strategic advisor, Asanté Partners, in April 2004, to assist us in our efforts to identify and implement strategic and financial alternatives. As discussed elsewhere in this proxy statement, on May 18, 2005, we entered into the merger agreement with ONI. If the merger is not completed, we will need to consider other alternatives, which could include liquidation and dissolution.

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, if 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. Before 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**

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

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

### **Revenue Recognition**

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

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We use distributors in countries where the distributors' experience and knowledge of local radiation and medical device regulatory issues is considered beneficial by our management. Under the distributor

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arrangements, there are generally no purchase commitments and no provisions for cancellation of purchases. Novoste or the distributor may cancel the distributor agreements at any time.

Revenue from sales of catheters directly to hospitals is recognized upon shipment after the hospital has received a Beta-Cath System and completed all licensing and other requirements to use the system. We recognize revenue from sales of catheters and stents at the time of shipment. We sell our catheters with no right of return except in cases of product defect or shipping errors.

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

## **Radiation and Transfer Devices and Amortization of Costs**

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

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

During the fourth quarter of 2004, we evaluated the recoverability of the carrying value for radiation devices and other assets to determine if an impairment charge was necessary. We performed this evaluation in accordance with the provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Based on this evaluation, we determined that the radiation devices were impaired with no fair value due to their specialized nature and recorded an impairment charge bringing their net book value to zero. Subsequent to December 31, 2004, no depreciation was recorded.

## **Asset Impairment**

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

During the fourth quarter of 2004, we 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 we only have 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 and expensed in the functions where the assets were used. At December 31, 2004, all of the specialized assets relating to the Beta-Cath product line

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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 net realizable value. At March 31, 2005, the carrying value of all long-lived assets is recorded at their estimated net realizable value.

## **Assets Held for Sale**

Following the announcement of a staged wind-down, we committed to a plan for the sale of certain assets in accordance with the wind-down plan. The plan includes actively identifying and seeking buyers for these assets. In accordance with the provision of SFAS 144, assets held for sale are stated at estimated net realizable value and depreciation on these assets has been suspended (see also Note 6 to the unaudited consolidated financial statements).

## **Employment Termination Costs**

As part of the wind-down plan, we have provided incentives to certain of our employees to remain with us to manage the wind-down. To receive these incentive payments, they are required to remain with us until their employment is terminated. We account for these termination benefits in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities* (see also Note 15 to the unaudited consolidated financial statements).

## **Stock-Based Compensation**

We use the intrinsic value method for valuing our awards of stock options and restricted stock and recording the related compensation expense, if any, in accordance with APB No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. We grant 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 (expense reduction) is recognized for increases (decreases) in the estimated fair value of common stock for any stock options with variable terms. No compensation expense is recognized for stock option grants to employees for which the terms are fixed and the exercise price is equal to the fair market value of the shares at the date of the grant.

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

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

## **Allowance for Doubtful Accounts**



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

### **Inventories**

Inventories are stated at the lower of cost or market value on a first-in, first-out (FIFO) basis. Provisions are recorded for excess or obsolete inventory equal to the cost of the inventory. Shelf-life expiration or replacement products in the marketplace may cause product obsolescence. If actual product demand and market conditions are

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less favorable than those projected by management, additional provisions might be required which would negatively impact operating profits. Novoste evaluates the adequacy of these provisions quarterly.

**RESULTS OF OPERATIONS****Comparison of Quarters Ended March 31, 2005 and 2004***Net Sales and Gross Margin*

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

	<b>Three Months Ended March 31</b>		
	<b>2005</b>	<b>2004</b>	<b>Increase (decrease)</b>
Net sales:			
United States	\$ 2,323	\$ 5,959	(61.0%)
Rest of world	1,090	1,066	2.3%
<b>Total net sales</b>	<b>3,413</b>	<b>7,025</b>	<b>(51.4%)</b>
Cost of sales	4,118	3,953	4.2%
<b>Gross margin (loss)</b>	<b>\$ (705)</b>	<b>\$ 3,072</b>	<b>(123.0%)</b>

Net sales decreased 51% in the first quarter from the same period in the prior year. This decrease is due to the effectiveness of drug-coated stents in reducing in-stent restenosis during the early months following the implant of the stents, thus reducing the demand for Novoste's products. The completion of the Guidant transaction in the second quarter of 2004 had a positive effect in the United States on the first quarter of 2005, with revenue from radiation devices increasing 700% above the first quarter of 2004 due to the addition of former Guidant customers and existing customers who paid for service contracts. Catheter revenue in the United States for the quarter ended March 31, 2005 was down 79% from the same period in the prior year. Rest of World sales have increased slightly because drug-eluting stents are not as prevalent within the European medical community and several former Guidant customers converted to the Beth-Cath system. We expect revenue from all sources to decline as the wind-down proceeds into the completion phase.

In the quarter ended March 31, 2005, cost of sales increased approximately 4.2% from the same period of the prior year due to an accrual of \$1,324,000 to recognize the estimated remaining minimum purchase commitments due to a supplier. Absent this accrual, costs would have declined 29% from the significant reduction in revenues and the corresponding reduction of costs variable to sales. However, the reduction in total costs was not proportionate to the decline in revenues due to the relatively high fixed costs associated with the manufacturing and service operations. During the fourth quarter of 2004, we recorded an impairment charge, which reduced all long-lived assets to net realizable value (see Note 14 to the unaudited consolidated financial statements). This action has a favorable effect on cost of sales, eliminating approximately \$1,000,000 of depreciation and amortization cost per quarter. However, cost of sales for the quarter ended March 31, 2005 includes increases of

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\$761,000 for reserves for slow moving and excessive inventory and \$275,000 for minimum payments to AEA for contractual obligations under the AEA Supply Agreement compared to the quarter ended March 31, 2004.

The 123% decline in gross margin for the first quarter of 2005 was a result of the revenue decline coupled with relatively high fixed costs associated with manufacturing and service operations. With the elimination of depreciation and amortization associated with long lived assets, which are now fully expensed as a result of the impairment charges, and the cost reductions associated with the wind-down plan being implemented, we expect gross margin to remain relatively constant as a percentage of revenue, but to decline in dollar terms due to a further decline in sales.

**Table of Contents****Operating Expenses**

Operating expenses consisted of the following (in thousands):

	<b>Three Months Ended March 31</b>		
	<b>2005</b>	<b>2004</b>	<b>Increase (decrease)</b>
Operating expenses:			
Research and development	\$ 434	\$ 2,475	(82.5%)
Sales and marketing	2,702	3,489	(22.6%)
General and administrative	2,878	1,800	59.9%
<b>Total operating expenses</b>	<b>\$ 6,014</b>	<b>\$ 7,764</b>	<b>(22.5%)</b>

At the end of the first quarter of 2004, we implemented a reduction in force, eliminating 84 positions across all functions. This reduction lowered annual operating costs by approximately \$6,000,000. During the first quarter of 2004, approximately 59 of the individuals left Novoste, with the remaining individuals leaving during the second and third quarters. As part of the wind-down plan announced in February 2005, approximately 50 additional positions were eliminated in the first quarter 2005. Employment termination costs of \$2,023,000 are included in the operating costs for the three months ended March 31, 2005.

The 83% decrease in research and development expenses for the first quarter of 2005, compared to the same period of the prior year, is in the area of clinical trials and product development. All clinical trials and product development activity have been discontinued and the only activity is post- procedure monitoring. The internal product development staff was released with the reduction in force in March 2004, and development efforts using outside firms have been suspended. We expect costs of this area to decline as the monitoring of closed clinical trials is completed.

The 23% decrease in sales and marketing expense for the first quarter ended March 31, 2005, compared to the same period of the prior year, is due to reduced sales and marketing personnel, and to significantly lower variable expenses related to lower revenues, principally commissions and travel expenses. All sales and marketing positions in the U.S. were eliminated in February 2005. We expect these expenses to decline, as sales personnel in Europe will exit the Company over the next several months.

The 60% increase during the first quarter of 2005, compared to the same period of the prior year, for general and administrative expenses is due to employment termination costs (see Note 15 to the unaudited consolidated financial statements) and professional fees associated with the evaluation of strategic alternatives.

**Other Income and Expenses**

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Other income for the first quarter of 2005 was \$165,000 compared to \$78,000 for the same period in the prior year. This net increase for the three months ended March 31, 2005 arose primarily from slightly higher interest rates and a shift to slightly longer maturities, which enjoy higher returns.

### *Net Loss*

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

	<b>Three Months Ended March 31</b>		
	<b>2005</b>	<b>2004</b>	<b>Increase (decrease)</b>
Net loss	\$ (6,554)	\$ (4,614)	\$ (1,940)
Net loss per share basic and diluted	\$ (0.40)	\$ (0.28)	\$ (0.12)

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The increase in net loss of \$(0.12) per share for the first quarter ended March 31, 2005, compared to the same period of 2004, was the net result of significantly lower revenues, the accrued estimated remaining minimum purchase commitments due to a supplier and the impact of employment termination costs and other expenses related to the evaluation of strategic alternatives and the wind-down of the VBT business. Net loss in the first quarter ended March 31, 2005 was positively effected by the elimination of depreciation and amortization expense along with the lower overhead cost structure resulting from the cost reduction initiatives implemented in earlier periods, and that are ongoing. During execution of the wind-down plan, we expect to continue to incur net losses.

**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):

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

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 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 us 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 our VBT 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.

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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.

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

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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%)
Restructuring and impairment charge	1,719		
	<u>          </u>	<u>          </u>	
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):

	<b>Year Ended December 31</b>		
	<b>2004</b>	<b>2003</b>	<b>Increase (decrease)</b>
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.

**Table of Contents***Net Loss*

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

	<b>Year Ended December 31</b>		
	<b>2004</b>	<b>2003</b>	<b>Increase (decrease)</b>
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):

	<b>Year Ended December 31</b>		
	<b>2003</b>	<b>2002</b>	<b>Increase (decrease)</b>
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%

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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 Novoste's Consolidated Notes to the Financial Statements). 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.

**Table of Contents****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%)
Sale and marketing	19,485	26,875	(27.5%)
General and administrative	8,237	8,335	(1.2%)
Restructuring and impairment charge			
<b>Total operating expenses</b>	<b>\$ 39,708</b>	<b>\$ 48,510</b>	<b>(18.1%)</b>

*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%)
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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.

**Table of Contents****LIQUIDITY AND CAPITAL RESOURCES****Cash Flows for the Three Months Ended March 31, 2005*****Operating***

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

	<b>Three Months Ended March 31</b>	
	<b>2005</b>	<b>2004</b>
Cash flows from operating activities:		
Net loss	\$ (6,554)	\$ (4,614)
Depreciation and amortization of property and equipment		637
Amortization of capitalized disposal costs	33	33
Depreciation of radiation and transfer devices		1,099
Other non cash items	72	(29)
Net change in operating assets and liabilities	2,122	513
<b>Net cash used in operating activities</b>	<b>\$ (4,327)</b>	<b>\$ (2,361)</b>

The net loss in the first three months of 2005 consumed \$4,357,000 of cash to fund operating activities. This compares to \$2,361,000 of cash used in the same period of 2004. The changes in operating assets and liabilities are consistent with the decline in business volume. Depreciation of property and equipment has been eliminated as all assets are considered to be impaired and held for sale. Included in the change in operating assets for the first three months of 2005 was \$930,000 generated from a reduction in receivables, compared to \$2,361,000 for the same period of 2004. Receivables are being collected faster than they are replaced by declining billing. Inventory declined due to the suspension of production in the face of declining demand, and increase of inventory reserves associated with surplus materials. Funds were generated by the collection of receivables and an increase in accrued expenses and accounts payables of \$593,000 during the quarter ended March 31, 2005. The increase in accrued expenses was due to the recording of minimum payment obligations arising from the AEA agreement. During the quarter ended March 31, 2004, accounts payables and accrued expenses declined \$1,893,000 as business declined. Unearned revenue related to the billing of service agreements (see Note 7 to the unaudited consolidated financial statements) decreased by \$568,000 in the first quarter of 2005, due to the declining VBT activity.

***Investing***

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

	<b>Three Months Ended March 31</b>	
	<b>2005</b>	<b>2004</b>
Cash flows from investing activities:		
Maturity/sale of short-term investments	\$ 7,158	\$ 3,504
Purchase of short-term investments	(1,283)	(2,035)
Purchase of property and equipment, net		(152)
Purchase of radiation and transfer devices		(573)
<b>Net cash provided by investing activities</b>	<b>\$ 5,875</b>	<b>\$ 744</b>

Investments have been liquidated to fund losses in operations. No cash was used to purchase property and equipment in the three months ended March 31, 2005, as compared to the same period of 2004, primarily due to lower revenue and the implementation of the wind-down plan. Also, no cash was used to purchase radiation source trains and transfer devices compared to the same period in the prior year due to the declining VBT business. This decrease in purchases is due to the existence of radiation source train inventory levels that will be adequate to meet the needs of Novoste for the foreseeable future.

#### ***Financing***

During the quarter ended March 31, 2005, we had no proceeds from the issuance of its common stock as a result of option exercises, compared to \$7,000 in the first quarter of 2004 when employees exercised stock options.

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In August 2001, the Company obtained a \$10 million revolving line of credit, which was extended by agreement from time to time. On May 27, 2004, we 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, we terminated the borrowing agreement with the financial institution and no obligations related to the agreement exist at March 31, 2005. At March 31, 2005, we had \$75,000 in outstanding letters of credit, which are secured by a certificate of deposit.

**Cash Flows for the Year Ended December 31, 2004**

During the year ended December 31, 2004, our 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.

***Operating activities***

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

	<b>Year Ended December 31</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
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	1,248	1,521	(85)
Prepaid expenses and other current assets	(290)	508	36
Other assets	508	890	(285)
Accounts payable	(33)	(753)	(2,033)
Accrued expenses	(2,658)	(3,527)	(1,001)
Unearned revenue	1,723	(2,258)	(387)
<b>Net cash provided by (used in) operating activities</b>	<b>\$ (5,910)</b>	<b>\$ 9,192</b>	<b>\$ 10,709</b>

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



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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 2003 and 2002 generated operating cash, as revenues were not declining and there were significant non-cash charges such as depreciation and amortization of radiation and transfer devices acquired in earlier years.

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### ***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.

### ***Financing activities***

Our 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 us 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 net from the issuance of common stock offset by the purchase of treasury stock and repayment of capital lease obligations.

### **Liquidity**

Our principal source of liquidity at March 31, 2005, consisted of cash, cash equivalents and short-term investments of \$24,662,000, compared to \$29,060,000 at December 31, 2004.

During the remainder of 2005, we expect to allocate resources to implement the VBT wind-down plan including funding contractual obligations, and advisory services including accounting and legal matters related to evaluation of our strategic options. We expect that our existing cash reserves will be sufficient to fund any cash used by operations and to meet our liquidity and spending needs at least through the end of the wind-down plan, sometime in late 2005.

Our future liquidity and capital requirements will depend upon numerous factors, mainly the risks discussed elsewhere in this proxy statement in the section entitled **Risk Factors** **Risks Related to Novoste**.

### **Commitments**

At March 31, 2005, We had commitments to purchase \$2,432,000 of products and services, primarily arising from contractual obligations related to radiation production stand-by fees and decommissioning of the radiation production facility. Of this amount, \$1,913,000 has already been recorded as an accrued expense as of March 31, 2005. The decline in commitments compared to \$10,992,000 at March 31, 2004, is consistent with the trend of our contracting business that requires less replacement of inventories and radiation devices and settlement of other obligations, such as Bebig (see below).

On October 14, 1999, we signed a development and manufacturing supply agreement with AEA for a source of radioactive supply and for the development of a smaller diameter radiation source. The agreement provided for the construction of a production line that was placed into service in October 2002. In addition, the agreement provides for joint ownership of all intellectual property arising from the development work and requires that AEA manufacture vascular brachytherapy sources only for us. The agreement contains minimum payment obligations, which Novoste has accrued \$1,324,000 for the quarter ending March 31, 2005 and expensed in cost of sales, due to the determination that the remaining contractual payments will not likely result in any economic benefit to us (see Note 14 to unaudited consolidated financial statements). On March 9, 2005, we provided the required notification to terminate the contract eighteen months before expiration of the agreement, in September 2006. At the termination of this agreement, Novoste is obligated for the expense of decommissioning the production facility. These expected costs have been accrued and are being expensed in cost of sales in accordance with SFAS 143, *Accounting for Asset Retirement Obligations*. The minimum payment obligations and the decommissioning costs are subject to negotiation and settlement with AEA.

On June 20, 2001, we amended our manufacturing and supply agreement with Bebig Isotopen-und Medizintechnik GmbH (Bebig), a German corporation, to manufacture and supply us with radioactive sealed

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Strontium-90 seed trains. During each calendar year of the four-year contract, we guaranteed minimum annual payments to Bebig of varying amounts over the term of the agreement and will provide up to \$250,000 for decommission expense of the production facility. All product purchases are credited against the annual guaranteed payment. At March 31, 2005, all purchase obligations had been satisfied and \$150,000 of the obligation for decommissioning remained to be paid. The term of this agreement ended on June 19, 2005 and all Bebig obligations have now been fulfilled.

We have entered into a license agreement with a physician pursuant to which he is entitled to receive a royalty on the net sales of the Beta-Cath System (excluding consideration paid for the radioactive isotope), subject to a maximum aggregate payment of \$5,000,000. Royalty fees earned by the physician were \$22,000 and \$69,000 for the three months ended March 31, 2005 and 2004, respectively. Earned royalties are paid within 60 days following the end of the quarter. As of March 31, 2005, an aggregate amount of \$2,185,000 has been earned under the license agreement and has been expensed as costs of sales.

On January 30, 1996, we entered into a license agreement whereby Emory University assigned its claim to certain technology to us 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 us, which occurred in 1998, minimum royalties were due to Emory University in the following amounts: year 2 after the first commercial sale \$10,000; year 3 \$15,000; year 4 \$25,000; and years 5-10, \$50,000 per year. The royalty agreement term is consistent with the life of the related patent and applies to assignments of the patent technology to a third party. Royalty fees earned by Emory University were \$60,000 and \$142,000 for the three months ended March 31, 2005 and March 31, 2004 respectively, and have been expensed as cost of sales. Earned royalties are paid within 60 days following the end of the quarter.

On April 22, 2004, we signed an asset purchase agreement with Guidant pursuant to which we acquired information regarding Guidant's vascular brachytherapy business, including the customer list of Guidant in the United States and Canada. We paid the sum of \$2,500,000 to Guidant at the signing of the transaction and have agreed to pay 5% on its net sales of all vascular brachytherapy products in the U.S. and Canada, up to an additional payment of \$4,000,000 (see Note 8 to unaudited consolidated financial statements). Under this agreement, Guidant has earned \$98,000 for the three months ended March 31, 2005 and \$287,000 since the execution of the contract.

We have made commitments to the approximately 40 employees who remained at March 31, 2005, to manage the wind-down of the VBT business. Of the \$4,407,000 expected costs for employment termination (see Note 15 to the unaudited consolidated financial statements), approximately \$2,956,000 relate to these commitments, of which \$950,000 has been recorded as an accrued expense as of March 31, 2005 and cover severance pay, outplacement assistance, and retention incentives. These expenses are being accrued over the period of expected employment.

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
<b>Contractual Obligations</b>					
Operating Leases	\$ 414	\$ 369	\$ 45	\$	\$
Purchase Obligations	1,956	1,311	645		

Total	\$ 2,370	\$ 1,680	\$ 690	\$	\$
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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.

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**OFF-BALANCE SHEET ARRANGEMENTS**

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

**RECENT ACCOUNTING PRONOUNCEMENTS**

In 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 us 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 by January 1, 2006.

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### **INFORMATION ABOUT ONI**

#### **BUSINESS OF ONI**

##### **Overview**

Founded in 1997, ONI develops, manufactures and markets dedicated-purpose magnetic resonance imaging, or MRI, systems. ONI's first product, the OrthOne system, is a compact, high-field 1.0 Tesla MRI system for imaging of extremities. ONI believes that the OrthOne system provides images that are superior in quality to those of low-field extremity systems and similar to those of whole-body systems installed in diagnostic imaging centers or hospitals, but for approximately one-third of the cost of a new whole-body system and a fraction of the size.

The key characteristics of the OrthOne system include its compact size, cost, hospital-grade image quality and suitability for orthopedic applications. ONI believes these characteristics make the OrthOne system suitable for:

Orthopedic practices seeking to improve patient care continuity and generate ancillary revenues by purchasing compact, economical, in-office, high-field MRI systems; and

Diagnostic imaging centers and hospitals seeking to increase MRI scanning capacity and efficiency at reduced capital costs by offloading extremity scans from overburdened whole-body MRI systems onto more compact, dedicated-purpose MRI systems.

ONI is in the process of developing a second dedicated-purpose MRI system intended to address a broader range of applications than the OrthOne system. ONI expects to introduce the new MRI system by the end of 2007.

#### **Industry Background**

##### *MRI Technology and Equipment*

MRI is a medical diagnostic technique that creates images of the human body using the principles of nuclear magnetic resonance. MRI technology was first presented in 1974, and MRI systems were first used on patients in 1983. Until the invention of MRI, the only methods of acquiring images from inside the human body involved the use of ionizing radiation, radioactive isotopes or ultrasound waves.

MRI involves the use of high-strength magnetic fields to generate computer-processed images of parts of the body, including bones, arteries and veins, from various angles and directions, without surgical intervention and in a relatively short period of time. This versatile, powerful and sensitive tool creates maps of biochemical compounds within various cross-sections of the human body. These maps give basic biomedical and anatomical information that may allow early diagnosis of many diseases.

MRI systems provide equivalent anatomical resolution and superior contrast resolution to that of x-ray and computerized tomography, or CAT or CT, scanners. MRI systems produce functional information similar to that of positron emission tomography, or PET, scanners but with better anatomical detail. MRI images are generally superior to x-ray images because MRI can distinguish variations in soft tissue more accurately.

Currently available MRI systems create images of varying quality, a factor important to many users of MRI systems. The primary indicator of image quality involves the strength, measured in Tesla, of the magnetic field created by the magnet incorporated in the system. MRI systems are generally divided into three categories based on the magnetic field strength they generate. The following table provides information regarding the types of



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customers for MRI systems of various magnetic strengths and the primary considerations of those customers in purchasing such systems:

Magnet Strength	Tesla	Customers	Primary Considerations
High-field	≥ 1.0	Hospitals, outpatient radiology departments, diagnostic imaging centers and research facilities	Image quality, cost, size and weight
Mid-field	0.5-0.9	Hospitals, outpatient radiology departments and diagnostic imaging centers	Cost
Low-field	< 0.5	Diagnostic imaging centers and physician s offices	Cost

All MRI systems are able to distinguish between soft and hard tissue, but soft-tissue differentiation improves as the strength of the magnet increases. High-field systems typically offer faster imaging speed, higher quality images, and a larger number of addressable applications. Because they facilitate faster and more accurate diagnoses, high-field MRI systems are generally more appealing to MRI service providers. Although high-field, whole-body MRI systems are typically the best in terms of imaging speed, image quality and breadth of addressable applications, they are also more expensive. ONI believes that the average selling price of a typical new system generally ranges between \$1,400,000 and \$2,000,000, depending on the strength of the magnet and the other options selected by the customer. High-field, whole-body MRI systems also require large, heavy magnets that generate extensive magnetic fields. As a result, these systems generally require a sizable installation area, reinforced flooring and substantial shielding, all of which can result in considerable facility upgrade costs. Because of these factors, whole-body systems have been sold primarily to diagnostic imaging centers and hospitals that generally have access to more capital and sufficient space. ONI believes the high costs and large space requirements of whole-body systems have resulted in purchase delays by diagnostic imaging centers and hospitals and have strongly discouraged purchases by smaller institutions and orthopedic practices.

The low-field and mid-field categories of MRI systems consist of lower-cost systems, mobile systems and low-field extremity systems. These systems have historically had inferior image quality and have experienced moderate success in selling to hospitals and research facilities. Low-field MRI systems typically target orthopedic practices. Because low-field MRI systems use less powerful magnetic fields, they generally produce lower quality images with longer scanning times.

Because of size, weight, shielding, power supply and space requirements, whole-body MRI systems require site planning and installation services. Prior to installation, customers must conform their sites to the required specifications. Site preparation for any MRI system can take several months. Generally, MRI systems require magnetic shielding to protect bystanders within a specified control zone, as well as radio frequency shielding, or RF shielding, to prevent outside radio waves from interfering with the scanning. In addition, ONI believes that whole-body MRI systems generally require at least 800 square feet of space for the recommended installation. ONI believes orthopedic practices, diagnostic imaging centers and hospitals are looking for opportunities to expand their current offerings of MRI scanning services, but in a manner that minimizes space requirements, initial purchase and installation costs, and ongoing service and maintenance costs.

*MRI Equipment Market*

A June 2005 article on the state of the radiology industry in *Decisions in Imaging Economics*, an imaging technology journal, reported that in 2003 MRI equipment sales were estimated by a consulting firm to reach \$1.1 billion in 2005. Hospitals and diagnostic imaging centers have been the primary buyers of MRI equipment. These buyers have purchased primarily whole-body systems, either of high-field or lower field strengths. A 2004 report by IMV Medical Information Division, Inc., a marketing research and consulting firm with a subspecialty in medical imaging and therapy markets, estimated that 7,110 MRI systems were installed in the United States at the time of the report (excluding mobile systems), representing 3,400 systems in hospitals and 3,710 systems in non-hospital settings, including diagnostic imaging centers. The report indicated that at the time of the report high-field 1.5 Tesla MRI systems constituted 60% of the installed base of MRI systems (excluding mobile



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systems). The report also estimated that in 2003 approximately 24.2 million total MRI scans were performed. ONI believes that approximately 20% of these scans were performed on upper and lower extremities.

ONI believes that, as a result of the substantial expense and siting requirements for whole-body MRI systems, orthopedic practices have purchased relatively few MRI systems, and the systems they have purchased have been primarily low-field systems because of their lower cost and smaller size. The lower field strength of these systems often produces lower-quality images, which tends to limit customer demand. Without on-site, high-quality MRI scanning capability, physician practices have had to refer their patients to radiologists in hospitals or diagnostic imaging centers with high-field MRI systems. This need to refer patients to other physicians outside the practice typically results in the delay of diagnoses, increased patient anxiety, inconvenience to the patient forced to travel on a separate occasion to a different facility, and the loss of revenue by the referring physician.

Hospitals and diagnostic imaging centers face different challenges in providing MRI scanning services. The breadth of diagnostic services that these organizations offer generally requires that they invest in high-field, whole-body MRI systems so that they can provide MRI scans of any part of the human body. These whole-body systems are commonly used to perform all of the organization's MRI scans, even in cases where only a scan of an extremity is needed. During periods of high demand, these systems can become significantly overburdened, leading to delays in diagnoses and inconvenience to patients. Nonetheless, ONI believes that the high investment costs of these whole-body systems make it difficult for hospitals and diagnostic imaging centers to respond quickly to increases in demand for MRI scanning services.

ONI believes that a market opportunity exists for a compact MRI system that offers hospital-quality images at a lower price and that can be installed in an office environment without the same extensive site preparation and space requirements as a whole-body system. ONI further believes that physicians able to offer in-office, high-field MRI scans can enhance practice revenues with ancillary income, accelerate diagnoses, reduce patient anxiety and inconvenience, and commence treatment more seamlessly and at an earlier stage. An affordable, compact, high-field MRI system can address the needs of a variety of market segments:

*Orthopedic practices.* These practices often have limited budgets and are commonly located in office environments where the reinforcements and shielding necessary for a large, whole-body MRI system are impractical. ONI believes that these practices typically perform scans in a volume that would not make an investment in a whole-body system cost-effective.

*Diagnostic imaging centers.* These centers require high-quality imaging but try to offer imaging services as cost-effectively as possible.

*Hospitals.* Hospitals require high-quality imaging and also seek to maximize the efficient use of their often overburdened whole-body MRI systems. Hospitals could benefit from a system that would enable them to increase capacity at a lower cost.

Such a system would make the benefits of diagnostic MRI imaging more widely available to patients by facilitating the migration of MRI scanning from hospitals to physician practices, much in the same way that more compact and economical ultrasound equipment substantially broadened the availability of ultrasound imaging in smaller physician practices.

ONI estimates that, in 2002, there were more than 4,100 orthopedic practices with four or more physicians, 3,400 hospitals and 1,900 diagnostic imaging centers operating in the United States.

*Reimbursement*

The United States Department of Health and Human Services Centers for Medicare and Medicaid Services, or CMS, the government agency that administers Medicare and Medicaid, has authorized reimbursement for MRI scans under the terms of the Medicare program. Periodically, CMS adjusts the reimbursement rates for medical procedures, including MRI scans, to reflect the costs incurred by health care providers to perform the procedures. In addition, many private insurance companies have authorized reimbursement for MRI scans.

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### *Certificate of Need*

Certain states, particularly in New England, have instituted Certificate of Need requirements to ensure that new healthcare services and facilities are developed only as needed, based on publicly-developed measures of cost effectiveness, quality of care and geographic and financial access to care. In these states, MRIs can be purchased only after complying with the Certificate of Need process, which could prohibit potential customers from purchasing the diagnostic equipment that they seek.

### **The ONI Solution the OrthOne System**

The OrthOne system is a compact, high-field 1.0 Tesla MRI system for imaging of extremities. The OrthOne system provides images that ONI believes are superior in quality to those of low-field extremity systems and similar to those of whole-body systems, but for approximately one-third of the cost and a fraction of the size. The OrthOne is designed for use by orthopedic practices, hospitals and diagnostic imaging centers.

ONI began developing the OrthOne system in mid-1997. ONI obtained clearance from the United States Food and Drug Administration, or the FDA, to market the OrthOne in August 2000 and began to generate revenue from sales in the fourth quarter of 2001. In June 2004, ONI obtained regulatory clearance to market the OrthOne system in the European Union.

### *The Features of the OrthOne System*

The OrthOne system was conceived as an MRI system that would allow orthopedic physicians to perform the majority of their extremity MRI scanning in their own offices. The OrthOne system consists of a proprietary compact design that features a specially designed cylindrical, high-field 1.0 Tesla magnet. The relatively small size of the magnet used in the OrthOne system enabled ONI to design the patient handling system with a movable chair. The chair can be easily adjusted to enable the patient to insert an extremity into the cylindrical magnet. This design provides greater flexibility in orienting the patient for optimal comfort, allowing imaging of hands, wrists, elbows, knees, ankles and feet. ONI believes this flexibility is a major benefit compared to closed, whole-body systems where patients in many cases complain of claustrophobia or discomfort.

The magnet used in the OrthOne system was specifically designed for high performance, compact size and weight, and ease of installation. The OrthOne system produces high resolution images showing relatively fine details in bone structures for joints and high sensitivity for stress fractures. ONI believes the quality of imaging of its OrthOne system derives from the high homogeneity and stability of the OrthOne magnet.

Installation of the OrthOne system is more flexible than that required for whole-body systems. The magnet used in the OrthOne system weighs less than 1,400 pounds, which alleviates the need for reinforced structure at the installation site. Because of its relatively compact size, the control zone protecting bystanders does not need to be greater than approximately 200 square feet. Installation of the OrthOne system typically requires only RF shielding, which is relatively less expensive and less complicated to install than other types of shielding. This relatively minimal shielding further reduces the need for specialized facility requirements and upgrades at the customer site. The OrthOne system uses standard electrical power.

*The Advantages of the OrthOne System for Orthopedic Practices*

The OrthOne system enables MRI scanning to take place within the offices of many orthopedic practices. ONI believes that its OrthOne system offers a number of key benefits to orthopedic practices, including the following:

*Additional source of revenue.* ONI believes that in-office scanning can provide an additional source of revenue for the orthopedic practice and dramatically reduce the need for physicians to make outside referrals to obtain MRI diagnostic images for their patients.

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*More attractive pricing.* ONI believes that the costs associated with the initial purchase, site preparation and ongoing maintenance of the OrthOne system are significantly lower than those of new high-field, whole-body MRI systems. ONI currently offers the OrthOne system at a list price of \$495,000, and ONI estimates that installation of the OrthOne system, including site planning and preparation, usually costs less than \$100,000.

*Increased patient comfort and convenience.* With on-site scanning capability, orthopedic practices have the opportunity to perform scans during the patient's initial office visit, enabling faster diagnoses and treatment, reducing patient anxiety arising from delayed diagnoses and reducing the need for additional visits except in cases where pre-authorization of payment is required. MRI scans using the OrthOne system take less time than a whole-body scan. Moreover, the OrthOne system requires the patient to insert only an extremity into the cylindrical magnet, rather than the patient's entire body, thereby reducing or eliminating the anxiety associated with claustrophobia that some patients experience with whole-body systems.

*Compact size and light weight.* The OrthOne system is small enough and light enough to be installed in the offices of most physician practices. ONI believes that the larger size of and extensive site preparation required for whole-body MRI systems generally make them impractical for installation in the offices of most orthopedic practices.

*Image quality.* As a high-field 1.0 Tesla MRI system, ONI believes that the OrthOne system produces images of a quality and clarity comparable to those produced by hospital-grade whole-body MRI systems.

*Ease of operation.* The operation of the OrthOne system requires relatively little special training, and scans are usually performed by the physician's radiological technologist.

ONI believes that the OrthOne system is attractive to diagnostic imaging centers and hospitals for many of the same reasons. Hospitals and imaging centers can use the OrthOne system as a dedicated-purpose imaging system to handle overflow from their existing whole-body systems, thereby increasing their overall MRI scanning capacity and efficiency at reduced capital costs.

## **ONI's Strategy**

ONI's objective is to become the leading supplier of dedicated-purpose MRI systems to orthopedic practices, hospitals and diagnostic imaging centers. Key elements of ONI's business strategy include:

*Target multi-physician orthopedic practices.* ONI believes its OrthOne system offers a combination of high image quality, pricing, size, weight and patient comfort that is attractive to orthopedic practices. ONI intends to direct the majority of its sales efforts toward orthopedic practices of four or more physicians, primarily because ONI believes that this segment of the market offers greater revenue opportunities. For these orthopedic practices, the purchase of a whole-body MRI system can be impractical or unprofitable, whereas a smaller, less expensive, dedicated-purpose MRI system can provide the practice with the ability to offer convenient, on-site scanning at a price that can generate incremental profits for the practice.

*Continue to market to hospitals and diagnostic imaging centers.* ONI also plans to continue to market the OrthOne system to hospitals and diagnostic imaging centers as a cost-effective supplement to existing whole-body MRI systems. ONI believes that the whole-body MRI systems operated by these potential customers are often overburdened with extremity scans, resulting in delays for neurological, thoracic and other scans that can only be performed on a whole-body system. By alleviating the need to use existing whole-body MRI systems for extremity scans, the OrthOne system offers an attractive, lower-cost solution that enables hospitals and diagnostic imaging centers to address their capacity constraints and improve scanning efficiency.

*Continue to expand ONI's direct sales force.* ONI intends to hire additional sales and marketing personnel to augment its existing sales force. The sale of each OrthOne system typically requires the investment of a



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significant amount of time and resources by ONI sales personnel. Because each sales person can effectively target only a limited number of customers, ONI believes that the small size of its direct sales force is limiting its ability to reach potential customers for its systems. ONI believes that increasing its direct sales force will enable it to accelerate the generation of revenue.

*Introduce a new MRI system.* ONI currently offers one MRI system, the OrthOne system. ONI intends to continue to invest in research and development with the goal of introducing a new MRI system by the end of 2007. The new MRI system is expected to address a broader range of applications than the OrthOne system.

*Penetrate international markets.* ONI expects to continue to pursue sales of its OrthOne system outside the United States, primarily in the European Union, where ONI recently received regulatory clearance to market the OrthOne system. ONI initially intends to pursue international markets by engaging a number of distributors rather than by attempting to establish an international direct sales force. The distributors are responsible for sales, marketing, installation and services. ONI believes that this approach will enable it to take advantage of international distributors' greater familiarity with, and expertise in, localized regulatory requirements, payment practices and customer needs.

*Leverage ONI's existing service organization.* ONI has invested in a field service organization with eight field service representatives located in major cities around the United States. ONI believes that its field service organization enables it to provide a more rapid response to requests for customer service or warranty coverage. Because the total installed base of OrthOne systems is relatively small, ONI believes that its present field service organization has the capacity to handle a larger installed base. As ONI sells additional OrthOne systems into areas where field service personnel are underutilized and as those systems begin to generate additional revenue from annual service maintenance contracts, ONI believes that the profitability of its service business will improve.

*Increase the breadth of ONI's product offerings.* In an effort to leverage ONI's direct sales force, ONI intends to seek to add complementary products and services to its current offerings. ONI may seek to develop additional product and service offerings through internal development efforts, licensing transactions or acquisitions of product lines, business divisions or companies.

## **Installation, Service and Warranty**

ONI installs and services its OrthOne system through its direct field service organization in the United States. As of May 31, 2005, ONI employed a total of 11 employees in its service organization, including eight employees located in major cities around the United States. Typically, the installation of an OrthOne system, including the planning and preparation of the site designated for the installation, takes several months. In both domestic and international markets, the customer is usually responsible for planning and preparing the site.

ONI typically warrants the OrthOne system against defects in materials and workmanship for a period of one year from the date of installation. After the initial warranty period, customers typically enter into single or multi-year service maintenance agreements under which ONI agrees to provide all necessary maintenance and services for a fixed fee. These services include quarterly preventative maintenance visits. ONI also repairs equipment that is out of warranty on a time-and-materials basis. In Europe, ONI's international distributors assume the responsibility for system installation, customer training and system warranty, and receive the benefit of any revenue from customer service maintenance contracts.

On a limited basis, ONI provides turnkey construction services to customers. In these cases, ONI acts as the general contractor to plan and prepare the customer site for installation of the OrthOne system and sub-contracts the site preparation to third parties. ONI generally passes these

subcontracting costs on to its customers without markup.

**Sales and Marketing**

The target markets for the OrthOne system are primarily orthopedic practices, diagnostic imaging centers and hospitals. In selected geographic regions, ONI also intends to continue to target leading medical institutions to use as reference accounts.

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ONI sells to customers in the United States through its direct sales force of approximately nine sales persons. ONI provides direct sales support from its headquarters in Wilmington, Massachusetts and through sales staff located in major cities around the United States. ONI uses an independent manufacturer's representative in Canada and other international distributors in Europe. Through March 31, 2005, ONI has sold three OrthOne systems in Europe. ONI had no sales in Europe before 2004.

In June 2004, ONI was certified by TUV Product Services as meeting the applicable requirements for ISO 9001, ISO 13485 and the Medical Device Directive 93/42/EEC of the European Union. ONI has qualified to apply the CE mark to the OrthOne system, which allows ONI to sell the system in participating countries in the European Union, subject to compliance with any additional local requirements in each country. For more information regarding regulatory compliance in the European Union and the United States, see Government Regulation.

## **Manufacturing**

ONI began production of the OrthOne system in the middle of 2001. ONI relies on outside contract manufacturers and vendors to supply the majority of the materials, components and subassemblies for the OrthOne system. These materials, components and subassemblies are either standard products or customized to ONI's specifications. ONI's in-house manufacturing operations, conducted at its Wilmington, Massachusetts facility, consist primarily of electronic assembly, final assembly, system integration, product testing and quality control. ONI manufactures OrthOne systems according to its forecast of sales and fills existing orders as customer sites become ready. ONI's strategy is to continue to rely on outside contract manufacturers and vendors to supply the various materials, components and subassemblies for the OrthOne system and to focus its internal resources on sales and marketing and research and development. ONI believes that this strategy should enable ONI to reduce fixed costs and capital expenditures.

ONI obtains the materials, components and subassemblies for the OrthOne system from a range of suppliers. Several components are from sole source suppliers. For example, GE Medical Systems Oxford Ltd., a subsidiary of General Electric Corporation, supplies the magnet and the gradient coil installed in the OrthOne system, and Cedara Software Corp., a Canadian software company, supplies key software incorporated into ONI's proprietary software platform and used in the OrthOne system.

If, for any reason, a supplier fails to meet ONI's quantity or quality requirements, or stops selling components to ONI or to a contract manufacturer of ONI at commercially reasonable prices, ONI could experience significant production delays and cost increases, as well as higher warranty expenses and product reputation problems. Because the key components and subassemblies of the OrthOne system are complex, difficult to manufacture and require long lead times, ONI may have difficulty finding alternative suppliers to produce these components and subassemblies on a timely basis. ONI has experienced shortages of some components and subassemblies in the past, which delayed shipments and the recognition of related revenue, and ONI may experience shortages in the future.

The design for the 1.0 Tesla magnet used in the OrthOne system was jointly developed by ONI and Magnex Scientific Ltd. In 2000, GE Medical Systems acquired Magnex. Under the agreement currently in effect between ONI and GE Medical Systems, the magnet will be manufactured and offered by GE Medical Systems exclusively to ONI for the OrthOne system. GE Medical Systems may cease accepting orders from ONI by providing twelve months' written notice to ONI. If GE Medical Systems elects to cease accepting orders, ONI would have 90 days following the date on which it receives notice from GE Medical Systems of such election to place ONI's final order, which cannot exceed 150% of the number of magnet units accepted in the preceding 12 months. After April 1, 2006, GE Medical Systems need not provide notice of cancellation.

On August 17, 2004, ONI entered into a value added reseller agreement with Cedara under which Cedara supplies proprietary computer software to ONI for incorporation into other software installed in the OrthOne system. The agreement expires on August 17, 2007. Under the agreement,

ONI is required to pay a fixed license

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fee on a defined 36-month payment schedule in exchange for a stated number of licenses to the Cedara software. ONI is licensed to incorporate the Cedara software in the OrthOne system and sell the software as part of the OrthOne system on a worldwide basis to end users and distributors named in the agreement. End-user licenses granted by ONI to purchasers of the OrthOne system will not be terminated as a result of the expiration or early termination of the Cedara agreement.

ONI has limited manufacturing capability and limited experience in large-scale manufacturing. There can be no assurance that ONI will be able to develop or contract for additional manufacturing capacity on acceptable terms on a timely basis.

## **Research and Development**

ONI's research and development efforts have focused primarily on developing and enhancing the OrthOne system. ONI conducts its research and development activities primarily through its internal research and development and engineering employees and resources, but ONI periodically supplements those activities with outside consultants. In late 2004, ONI began developing a second dedicated-purpose MRI system intended to address a broader range of applications than the OrthOne system. ONI expects to introduce the new MRI system by the end of 2007. During 2004, ONI incurred research and development expenditures of approximately \$1,843,000, as compared to approximately \$1,783,000 during 2003 and approximately \$2,328,000 during 2002. ONI intends to continue to invest in research and development with a goal of building a leadership position in the high-field, dedicated-purpose MRI scanning industry.

## **Competition**

The market for MRI systems is intensely competitive and dominated by a small number of large, well-known companies, including GE Medical Systems, Hitachi Corporation, Philips N.V., Siemens A.G. and Toshiba Corporation. Suppliers of MRI systems generally offer either whole-body systems or extremity systems, and offer systems with either high-field, mid-field or low-field magnetic strength. These systems compete primarily on the basis of the following factors:

the quality of the image, with higher-field systems offering better image quality;

the cost of the system, with whole-body systems generally costing more than extremity systems;

the number and variety of addressable applications;

the minimum area needed to install the system and related shielding;

the cost and length of time to install the system;

ongoing support and maintenance costs;

the speed of image production;

patient comfort;

brand reputation; and

quality and speed of customer service.

In the orthopedic practice market, ONI competes primarily with Esaote SpA, an Italian manufacturer of low-field extremity systems, and with the manufacturers of whole-body systems, including GE Medical Systems, Hitachi Corporation, Philips N.V., Siemens A.G. and Toshiba Corporation. GE Medical Systems distributes Esaote's Artoscan and E-Scan systems in the United States. In the hospital and diagnostic imaging center market, ONI competes primarily with the manufacturers of whole-body systems. For more information regarding ONI's relationship with GE Medical Systems, see Manufacturing and Intellectual Property. There can be no assurance that manufacturers of whole-body systems will not enter the market for extremity systems. ONI's

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competitors have significantly greater financial, technical, manufacturing, marketing and managerial resources than ONI and might be perceived by customers as offering greater financial and operational stability than ONI.

Potential customers for MRI systems have budgetary limitations on their investments in imaging technologies, and as a result ONI competes indirectly with suppliers of other imaging technologies, such as x-ray machines, PET scanners, CT scanners, ultrasound machines and nuclear medicine. Although each of these alternative technologies has certain attractive features, ONI believes that each alternative technology also offers medical professionals a significantly different mix of advantages and disadvantages and therefore often address different applications than MRI systems. For example, ultrasound machines are significantly less expensive than MRI systems but cannot match the high quality of images generated by MRI systems. Nonetheless, potential customers for MRI systems may choose to forego the purchase of an MRI system such as the OrthOne in favor of other imaging technology that the customer may find more suitable for its medical practice.

ONI also faces competition from companies that offer refurbished whole-body MRI systems. These refurbished systems are often available at a substantial discount to the cost of a new whole-body system, but otherwise have many of the same disadvantages as new systems. Refurbished systems also commonly require more extensive upgrades and maintenance, which can often be expensive.

## **Intellectual Property**

Certain core portions of the technology underlying magnetic resonance imaging are now in the public domain. ONI's design for the 1.0 Tesla magnet used in the OrthOne was jointly developed by ONI and Magnex Scientific Ltd. over approximately a three-year period. In 2000, GE Medical Systems acquired Magnex. Under the agreement currently in effect between ONI and GE Medical Systems, ONI and GE Medical Systems co-own the design of the OrthOne magnet, but each party otherwise retains ownership of its own confidential and proprietary information relating to the OrthOne magnet. For example, the agreement does not grant ONI any rights or access to GE Medical Systems' own processes, trade secrets or know-how relating to the manufacture of the magnet. Because GE Medical Systems has been manufacturing the OrthOne magnet for more than four years, these processes, trade secrets and know-how may be valuable, and a third-party manufacturer engaged by ONI to produce the OrthOne magnet might encounter difficulties in manufacturing the magnet as efficiently and effectively as GE Medical Systems without its assistance.

ONI's ability to compete effectively depends in part on its ability to protect the OrthOne magnet design and its other proprietary technology. ONI seeks to protect its proprietary technology primarily under laws affording protection for trade secrets and also seeks copyright and trademark protection for its products and developments where appropriate. Although ONI has not yet applied for any United States or foreign patents, it is beginning to implement a technology strategy that will include an assessment of its proprietary technology for which patent protection could be beneficial. At present, ONI relies primarily on trade secrets, technical know-how and other unpatented proprietary information relating to its product development and manufacturing activities. ONI also seeks to protect its trade secrets and proprietary information by requiring key employees to enter into agreements providing for the confidentiality of information and the assignment to ONI of rights to inventions made by them while employed by ONI. ONI enters into non-disclosure agreements with certain consultants and other suppliers to protect any of its confidential information delivered to them. ONI maintains controls over access to its technology and other proprietary information.

The steps ONI has taken to protect its proprietary technology may be inadequate to prevent others from using what ONI regards as its technology to compete with ONI. There can be no assurance that confidentiality agreements with employees, consultants and other parties will not be breached, that ONI will have adequate remedies for any breach or that ONI's trade secrets and other proprietary information will not otherwise become known. In addition, other companies could independently develop technologies that are similar or superior to ONI's technology or reverse engineer its products. Moreover, the laws of foreign countries in which ONI sells its products may afford little or no protection to its intellectual property rights.





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ONI does not conduct comprehensive patent searches to determine whether other persons may have patents or patent applications that cover any portion of ONI's products or technology. In an evolving technological environment, product development is inherently uncertain, and there may be numerous pending patent applications that may cover ONI's products or technology. Accordingly, other persons may have or obtain patents that will prevent, limit or interfere with ONI's ability to make, use or sell its products in the United States or international markets.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Any claim of infringement against ONI could cause it to incur substantial costs defending against the claim, even if the claim is invalid, and could distract the attention of ONI's management. If ONI's products or technology is found to violate third-party proprietary rights, ONI may be required to pay substantial damages. In addition, ONI may be required to re-engineer its products or seek to obtain licenses from third parties to continue to offer its products. Any efforts to re-engineer its products or obtain licenses on commercially reasonable terms may not be successful, which would prevent ONI from selling its products, and, in any case, could substantially increase its costs and have a material adverse effect on its business, financial condition and results of operations.

## **Government Regulation**

### *United States*

The OrthOne is regulated in the United States as a medical device. The manufacture and sale of medical devices are subject to extensive governmental regulations in the United States. Medical devices are regulated by the FDA under the federal Food, Drug, and Cosmetic 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 ONI 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 OrthOne system is a Class II device. ONI received FDA clearance to market the OrthOne system in August 2000 and began generating revenue from sales in the fourth quarter of 2001.

Any products manufactured or distributed 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 are subject to periodic inspections by the FDA. The Food, Drug, and Cosmetic Act requires device manufacturers to comply with good manufacturing practices regulations, called the quality systems regulations, or 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



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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, medical device reporting regulations obligate 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.

Product advertising is also subject to regulation by the Federal Trade Commission, or the FTC, 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 FTC'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.

ONI is also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire-hazard control and disposal of hazardous or potentially hazardous substances. ONI 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 ONI.

### *International*

In June 2004, ONI was certified by TUV Product Services as meeting the applicable requirements for ISO 9001, ISO 13485 and the Medical Device Directive 93/42/EEC of the European Union. ONI has qualified to apply the CE mark to the OrthOne system, which allows ONI to sell the system in participating countries of the European Union, subject to compliance with any additional local requirements in each country. Although the European Union's medical devices directive is intended to ensure free movement within the European Union of medical devices that bear the CE mark, many countries in the European Union 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 mark. Many European countries maintain systems to control the purchase and reimbursement of medical equipment under national health care programs, and the CE mark does not affect these systems.

### **Employees**

As of June 30, 2005, ONI employed 49 full-time employees, including 13 in sales and marketing, 11 in general field service roles, 10 in manufacturing and quality, nine in research and development, and six in general administration and finance. ONI also has seven temporary employees or consultants. ONI believes that its relationship with its employees is good.

### **Facilities**

ONI's headquarters and its research, manufacturing and administrative facilities are located in Wilmington, Massachusetts. ONI leases approximately 20,658 square feet of space under an operating lease that expires in October 2009. ONI has an option to renew this lease for an additional five-year period. ONI is currently negotiating to lease approximately 2,690 square feet of additional space. ONI believes that its current space, with the additional 2,690 square feet of space, will be adequate to meet its need for the foreseeable future.

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**ONI S REASONS FOR THE MERGER**

At its meeting on May 11, 2005, following detailed presentations by ONI s management and discussions with outside advisors, the members of the ONI Board of Directors present in person or by telephone at the meeting unanimously approved the merger agreement with Novoste and declared its advisability. In the course of making its decision to approve the merger agreement, the ONI Board of Directors consulted with ONI s management, as well as its outside legal counsel and its financial advisors. The ONI Board of Directors considered, among other things, the following material factors at its May 11, 2005 meeting and certain prior meetings referred to in the section entitled Background of the Merger:

In the course of reaching its decision to approve the merger agreement, the ONI Board of Directors considered the following factors as generally supporting its decision:

its understanding of ONI s business, operations, financial condition, earnings and prospects on a stand-alone basis and forecasted combined basis; including the availability and cost of additional capital to finance its businesses and development of its products;

its understanding of the current and prospective business environment in which ONI operates, including international, national and local economic conditions, the competitive and regulatory environment for MRI service providers generally, the technological trends in the MRI industry, and the likely effect of these factors on the combined company or, in the alternative, on ONI on a stand-alone basis; the ONI board of directors considered in particular that the competitive nature of the MRI industry made it more likely that ONI s prospects for growth would be enhanced if its business was well capitalized;

its understanding of Novoste s business, operations, financial condition, earnings and prospects on a stand-alone basis, in light of relevant factors, including the decision of Novoste to wind down or sell its business operations and to move away from actively pursuing the VBT business;

the expected ownership by the current holders of ONI s equity securities in the combined company;

the terms and conditions of the merger agreement, including the nature of the parties representations, warranties, covenants and agreements; in particular, the ONI board believed, after reviewing the merger agreement with its legal advisors, that the merger agreement offered ONI reasonable assurances as to the likelihood of completion of the merger, did not contain unusual conditions or other provisions, and did not impose unreasonable burdens on ONI, including the circumstances under which the merger agreement could be terminated and the impact of such a termination;

the terms and conditions of the loan by Novoste of \$3,000,000;

the proposed board and management arrangements of the combined company, under which the current President and Chief Executive Officer of ONI will become President and Chief Executive Officer of the combined company and be elected to the Novoste board of directors and four other ONI directors will join an enlarged Novoste board of directors, which the ONI board of directors believed would help position the combined company with strong and experienced leadership;

historical information concerning ONI s business, financial condition, results of operations, earnings, technology positions, management, competitive position and prospects on a stand-alone basis and forecasted combined basis;

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the relative exchange ratios provided in the merger agreement for the holders of ONI common stock and ONI Series A preferred stock and the termination of certain preferences and contractual rights of the holders of ONI Series A preferred stock upon completion of the merger;

current financial market conditions, including relative valuations of MRI companies and credit market considerations, which were generally perceived as favorable in the context of this acquisition;

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the impact of the merger on the employees of ONI, which was generally anticipated to be positive because of the broader opportunities that would be available to the employees;

information available to the ONI board of directors concerning other strategic alternatives as described above under Approval of Issuance of Shares in the ONI Merger Background of the Merger;

the increased liquidity expected to result from exchanging securities of a private company for publicly traded securities of Novoste, including the historical trading volume and prices of Novoste common stock and the fact that Novoste common stock is listed on the Nasdaq National Market;

the lack of material regulatory consents required to consummate the merger and the belief of ONI's management that the merger would otherwise be consummated in accordance with the terms of the merger agreement;

the expectation that the merger would qualify as a reorganization for U.S. federal income tax purposes and that, as a result, the exchange of ONI capital stock for Novoste common stock in the merger would be tax-free to holders of ONI common stock;

reports from management and financial advisors as to the results of their due diligence investigation of Novoste; and

the expectation that the merger could be completed within a reasonable time frame.

The ONI board of directors also considered a number of potentially negative factors in its deliberations concerning the merger agreement, including:

the risk that, because the exchange ratio under the merger agreement would be adjusted for changes in the cash on hand of Novoste and the performance of ONI, the per share value of the consideration to be paid to the current holders of ONI's equity securities at closing could be significantly less than the per share value of the consideration if the closing occurred on the date of signing the merger agreement;

the difficulties and management challenges inherent in completing the merger;

the risk that Novoste's financial performance may not meet ONI's expectations and therefore Novoste may have less cash at the closing than expected;

the risk that the merger might not be consummated and the possible adverse implications for customers, investors relations and employee morale under such circumstances;

the risk that Novoste will not meet new or existing Nasdaq National Market listing requirements at and after the closing of the merger;

the possibility that the effort required to plan for the merger might adversely affect the ability of ONI to meet its existing business performance targets;

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the merger agreement restricts ONI's ability to pursue alternatives to the merger; and

certain of the risks described under "Risk Factors" beginning on page 13.

The ONI board of directors also reviewed Novoste's SEC filings, numerous publicly available third party analyses and newspaper articles regarding the vascular brachytherapy industry in general and Novoste's business prospects and financial condition in particular.



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The ONI board of directors also considered that the fact that exchange ratio would adjust before the closing of the merger based on implied valuations of ONI and Novoste and that the terms of the merger agreement did include termination rights triggered expressly by a decrease in the value of the merger consideration. The ONI board of directors determined that this structure was appropriate and the risk acceptable in view of: the relative intrinsic values and financial performance of ONI and Novoste and the percentage of the combined company to be owned by former holders of ONI common stock; the inclusion in the merger agreement of other structural protections such as the ability to terminate the merger agreement in the event of a material adverse effect on the financial condition, assets, liabilities, business or results of operations of Novoste; and ONI's ability, under the limited circumstances specified in the merger agreement, to consider and participate in discussions and negotiations with respect to alternative proposals.

The foregoing discussion of the information and factors that the ONI board of directors considered is not intended to be exhaustive, but is meant to include the material factors that the ONI board of directors considered. In view of the complexity and wide variety of factors, both positive and negative, that the ONI board of directors considered, the ONI board of directors did not find it practical to, and did not attempt to, quantify, rank or otherwise assign relative or specific weights or values to any of the factors considered. In addition, individual members of the ONI board of directors may have given different weights to different factors.

In considering the various factors, individual members of the ONI board of directors considered all of these factors as a whole, and concluded that, on balance, the positive factors outweighed the negative factors and that they supported a determination to approve the merger agreement and declare its advisability.

**Table of Contents****EXECUTIVE OFFICERS AND DIRECTORS OF ONI****Executive Officers and Directors**

Set forth below are the names and certain information with respect to each of ONI's current directors and executive officers:

<b>Name</b>	<b>Age</b>	<b>Position</b>
David Hable (1)	50	Chairman of the Board of Directors
Robert L. Kwolyk	58	President, Chief Executive Officer and Director
Peter B. Roemer, Ph.D	50	Chief Technology Officer, Senior Vice President and Director
Darlene M. Deptula-Hicks	47	Chief Financial Officer, Executive Vice President and Treasurer
Ron Ramsey	55	Vice President of Sales
Srini Conjeevaram (1)	47	Director
Douglas P. Feick (1)(2)	40	Director
Stephen I. Shapiro (2)	60	Director
Bruce F. Wesson (2)	63	Director

(1) Member of the audit committee

(2) Member of the compensation committee

Each director continues to serve as a director until the next annual meeting and his or her successor is duly elected and qualified. ONI's executive officers are elected by, and serve at the discretion of, the ONI board of directors. There are no family relationships among the ONI directors and executive officers.

**David Hable** has been a director of ONI since August 2003. Mr. Hable has over 26 years of operational experience in the medical device industry. In 2004 and 2003, Mr. Hable served as President & Chief Operating Officer of BrainsGate LTD, a start-up company, based in Israel and engaged in the development of neuro stimulation technology. After beginning his career at Procter & Gamble, he joined Johnson & Johnson in 1979 and was promoted through positions of increasing responsibility in sales, marketing and new business development. From 1998 to 2003, Mr. Hable held the position of Worldwide President of Codman & Shurtleff, Inc., a wholly owned subsidiary of Johnson & Johnson, focused on neurosurgery. During the same period, Mr. Hable maintained a position on the DePuy Worldwide Management Board of Directors which oversaw all of Johnson and Johnson's orthopedic business in total joint replacement, spine, trauma and sports medicine. From 1994 until July 1998, Mr. Hable held the positions of Vice President of Marketing and a member of the Board of Directors of Johnson & Johnson Professional, Inc. and had responsibility for the combined orthopedic and neurosurgery businesses. Mr. Hable graduated from Southern Methodist University with a degree in Marketing.

**Robert L. Kwolyk** co-founded ONI in 1997 and has served as the President and Chief Executive Officer since its inception. Mr. Kwolyk has over 20 years experience in sales and marketing, business development, strategic planning and general management. He joined GE Medical Systems in 1977, in the sales and marketing organization, successfully managing global sales and marketing efforts for the MRI business from its inception. During his 17-year tenure at GE Medical Systems, he was also responsible for the company's business development efforts in Latin America and China. In 1994, Mr. Kwolyk joined Advanced NMR, Inc. as Vice President of Sales and Marketing and, subsequently, became Chief Operating Officer. He received his B.E. degree in Electrical Engineering in 1972 from Stevens Institute of Technology.

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**Peter B. Roemer PhD** co-founded ONI in 1997 and serves as Vice President and Chief Operating Officer. Dr. Roemer joined General Electric in 1983 as a scientist in the area of electromagnetic design as applied to rotating machinery and MRI systems. He was responsible for a number of technical developments that made important contributions to GE's MRI business and the industry at large. In 1990, Dr. Roemer was appointed manager of the MRI and the Image Guided Therapy Program in the Applied Physics Laboratory at GE and was responsible for

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directing GE longer range development activities in MRI. In 1994, Dr. Roemer joined Advanced NMR Inc., to develop a dedicated breast imaging system and to commercialize 3T systems under contract with GE. Dr. Roemer is the author or co-author of many scientific publications and 31 patents. He is a member of the International Society of Magnetic Resonance in Medicine and the American Physical Society. He received his BS degree in Electrical Engineering and a Ph.D. in Nuclear Engineering, both from the Massachusetts Institute of Technology.

**Darlene M. Deptula-Hicks** joined ONI in February 2002 as Executive Vice President and Chief Financial Officer and Treasurer. Previously from 1998 to 2001, she served as Executive Vice President and Chief Financial Officer and Treasurer of Implant Sciences Corporation, an early stage medical device company that had its initial public offering in June of 1999. She served as Corporate Controller of Abiomed, Inc., a publicly traded medical device company, from 1997 to 1998. From 1992 to 1996, Ms. Deptula-Hicks was the Vice President and Chief Financial Officer of GCA Corporation, semiconductor equipment manufacturer with revenues in excess of \$85 million. Ms. Deptula-Hicks currently serves on the Board of Directors and as Chair of the Audit Committee of IMCOR Pharmaceutical Company a public biotech company and serves on the Board of Trustees of the Rockingham County 4-H Foundation. Ms. Deptula-Hicks has over 25 years experience in financial management positions, primarily in the medical device sector, and holds a BS in Accounting from New Hampshire College and an MBA from Rivier College.

**Ron D. Ramsey** has served as ONI's Vice President of Sales, since 2004. Mr. Ramsey joined ONI in February 2001 as Western Region Sales Manager. Previously, from 1999 to 2001 he was the Western U.S. Sales Manager for Marconi Medical Systems and from 1995 to 1999 was the National Sales Manager for Fischer Imaging Corporation. Mr. Ramsey served as a full line sales rep and District Sales Manager for Toshiba Medical Systems from 1989 to 1995 and a full line sales representative for General Electric Medical Systems from 1984 to 1989. Mr. Ramsey has over 25 years of sales experience in the medical imaging market and holds a BS in Business from University of Tennessee.

**Srini Conjeevaram** has been director of ONI since August 2003. He is currently a General Partner of Galen Associates, a healthcare venture capital firm, and has been with them since January, 1991. Before his affiliation with Galen Associates, he was an associate in Corporate Finance at Smith Barney from 1989 to 1990 and a senior project engineer for General Motors Corporation from 1982 to 1987. Mr. Conjeevaram serves as a director of Derma Sciences, Inc. a public company, and Integrated Diagnostic Centers, a private company, and is a board observer to Acura Pharmaceuticals, Inc., a public company. He earned a Bachelor of Science degree in Mechanical Engineering from Madras University, Madras, India, a Master of Science degree in Mechanical Engineering from Stanford University, Stanford, California, and a Master of Business Administration in Finance from Indiana University, Bloomington, Indiana.

**Douglas P. Feick** has been a director of ONI since February 2002. Mr. Feick joined ChoiceStream in 2002 and is the Executive Vice President of Business Affairs and Finance and a member of the Board of Directors. Before joining ChoiceStream, from 1998 to 2001, Mr. Feick held several positions at Yahoo! Inc., most recently Vice President, Corporate Development for Yahoo! Inc. where he managed the domestic and international corporate development activities, including acquisitions, investments and strategic alliances. Before joining Yahoo! in June 1998, Mr. Feick served as General Counsel for WorldPlay Entertainment, Inc., an online, interactive games provider and a wholly owned subsidiary of America Online, Inc. From 1991 to 1997, Mr. Feick practiced corporate law with the law firm of Stradling, Yocca, Carlson & Rauth in Newport Beach, CA. Mr. Feick received his undergraduate degree in Business Administration from Miami University, Oxford, Ohio in 1987 and received his law degree from the University of Southern California School of Law in 1991.

**Stephen I. Shapiro** has served as a director of ONI since August 2003. Since 1999, he has been an independent consultant for venture capital firms, including 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, Becton Dickinson and Company. Mr. Shapiro received a B.S. degree in Chemical Engineering from the

Massachusetts Institute of Technology and an M.S. degree in Chemical Engineering from the University of



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California at Berkeley. Mr. Shapiro is also currently a director of Novoste. See Election of Directors Information as to Nominees and Continuing Directors.

**Bruce F. Wesson** has been a director of ONI since August 2003. Mr. Wesson joined Galen Associates in 1991 after serving as a Managing Director in the Corporate Finance Division at Smith Barney where he worked for over 23 years. Mr. Wesson joined Smith Barney in 1967. In 1976, Mr. Wesson was promoted to Managing Director, and four years later was elevated to Senior Vice President and Managing Director. During his tenure at Smith Barney, Mr. Wesson directed the Major Account Group and was Senior Managing Director in charge of the East Coast Region. Mr. Wesson was also Chairman of the Valuation and Opinion Committee for Corporate Finance. He currently serves as Chairman of the Board of Directors of QMed, Inc. and is a director of Crompton Corporation, Encore Medical, Inc., Acura Pharmaceuticals, Inc., and several privately held companies. He formerly served on the Board of Directors of CryoLife, Inc., a publicly company. Mr. Wesson serves on the Board of Trustees of Colgate University and is a past President of the Colgate University Alumni Corporation Board of Directors. He also serves as Vice Chairman of the Board of Trustees of the Overlook Hospital Foundation and is Chairman of the Investment Committee. Mr. Wesson holds a BA from Colgate University and an MBA from Columbia University.

## **Board and Committee Meetings**

During the fiscal year ended December 31, 2004, the ONI Board of Directors met seven times and acted by unanimous written consent one time. During fiscal 2004, each incumbent director attended at least 75% of the total number of meetings held by the ONI board and the committees of the ONI board on which he or she served. To the extent reasonably practicable, directors are expected to attend board meetings and meetings of committees on which they serve.

The ONI board of directors has two standing committees: the audit committee and the compensation committee. The membership of each committee of the ONI board is as follows:

### *Audit Committee:*

Srini Conjeevaram  
Douglas Feick  
David Hable

### *Compensation Committee:*

Douglas Feick  
Stephen Shapiro  
Bruce F. Wesson

## **Audit Committee**

The audit committee of the ONI board of directors is currently composed of Messrs. Conjeevaram, Feick and Hable. The audit committee provides the opportunity for direct contact between our independent auditors and members of the ONI board of directors; the auditors report directly to the committee. The committee assists the board in overseeing the integrity of the financial statements; compliance with legal and regulatory requirements; the independent auditor's qualifications and independence; and the performance of the independent auditors. The committee is directly responsible for appointing, compensating, evaluating and, when necessary, terminating the independent auditors. ONI is a privately held company and therefore the ONI board of directors has not been required to determine if any of the members of the audit committee qualify as an audit committee financial expert under the rules of the Securities and Exchange Commission. In addition, the ONI board of directors has not adopted an audit committee charter or a formal procedure for the treatment of complaints regarding accounting, internal accounting controls or auditing matters. The ONI audit committee met two times during fiscal 2004.

**Compensation Committee**

The compensation committee of the ONI board of directors is currently composed of Messrs. Feick, Shapiro and Wesson. The responsibilities of the compensation committee include providing recommendations to the board regarding the compensation levels of directors, approving, or recommending for approval by the board, the compensation levels of executive officers, providing recommendations to the board regarding compensation programs, administering employee benefit plans, including all incentive compensation plans and equity-based plans, authorizing grants under the ONI stock option plans, and authorizing other equity compensation arrangements. The compensation committee met two times during fiscal 2004.

**Table of Contents****COMPENSATION OF ONI S DIRECTORS AND EXECUTIVE OFFICERS****Director Compensation**

ONI pays its non-employee directors \$1,000 for each regular or special board meeting attended in person and \$250 for each regular or special board meeting attended by telephone. ONI does not pay additional compensation for service as chair of any committee or as a member of any committee of the board. Directors who are employees do not receive separate fees for their services as directors.

In January 2005, Messrs. Conjeevaram, Feick, Shapiro and Wesson received 15,000, and David Hable received 22,500, nonqualified options to purchase ONI common stock as compensation for their services as non-employee directors of ONI. These options were granted under the ONI 1997 incentive and non-statutory stock option plan, vest in full on the first anniversary of the date of grant and have a term of ten years. The initial exercise price of these options is \$0.26 per share, which is equal to the fair market value of the ONI common stock on the date of grant as determined by the ONI board of directors. For more information concerning director compensation of the combined company, see *Approval of Issuance of the Shares in the ONI Merger* *Interests of Certain Novoste and ONI Persons in the Merger*.

**Executive Compensation**

*Compensation summary.* The following table provides summary information concerning the compensation earned by ONI s chief executive officer and the three most highly compensated executive officers, other than the chief executive officer, for services rendered in all capacities for the fiscal years ended December 31, 2002, December 31, 2003, and December 31, 2004.

Other annual compensation in the form of perquisites and other personal benefits has been omitted because the aggregate amount of those perquisites and other personal benefits was less than \$50,000 and constituted less than ten percent of the executive officers respective total annual salary and bonus.

The column entitled securities underlying options represents shares of common stock issuable upon exercise of stock options granted under the ONI stock option plan.

**Summary compensation table**

Name and principal position	Year	Annual compensation			Long-term compensation	All other compen-
		Salary (\$)	Bonus	Other annual	Awards	sation (\$)
					Securities	



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			(\$)	compen- sation (\$)	underlying options (#)
Robert L. Kwolyk	2004	\$ 249,116			500,000
	2003	\$ 212,971			
President and Chief Executive Officer	2002	\$ 213,292			40,000
Peter B. Roemer	2004	\$ 238,039			400,000
	2003	\$ 212,054			
Chief Technology Officer and Senior Vice President	2002	\$ 212,375			40,000
Darlene M. Deptula-Hicks	2004	\$ 174,231	\$ 20,000		200,000
	2003	\$ 146,878	\$ 37,500		100,000
Chief Financial Officer, Executive Vice President and Treasurer	2002	\$ 116,627 <sup>(1)</sup>			50,000
Ron D. Ramsey	2004	\$ 203,332 <sup>(3)</sup>			\$ 6,564 <sup>(4)</sup>
	2003	\$ 191,685 <sup>(2)(3)</sup>			135,000 \$ 6,122 <sup>(4)</sup>
Vice President of Sales	2002	\$ 136,409 <sup>(3)</sup>			35,000 \$ 6,258 <sup>(4)</sup>

(1) Ms. Deptula-Hicks joined ONI in February 2002 and therefore values for 2002 are for only part of the fiscal year.

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- (2) Mr. Ramsey was Western Region Sales Manager for ONI until November 2003, when he assumed the position of Vice President of Sales. As such, his salary in 2002 and 2003 relates directly to his duties as Western Regional Sales Manager.
- (3) Amount includes sales commissions equal to \$47,563, \$89,077, and \$39,250 for the periods ended December 31, 2004, 2003, and 2002 respectively.
- (4) Represents auto allowance.

*Option grants in last fiscal year.* The following table provides information concerning stock options granted to the ONI executive officers named in the summary compensation table.

In fiscal 2004, ONI granted to its employees options to purchase an aggregate of 1,342,900 shares of common stock under the ONI 1997 incentive and non-statutory stock option plan. In accordance with the stock option plan, all options were granted with an exercise price equal to fair market value as determined by the ONI board of directors on the date of grant.

Amounts reported in the last two columns represent hypothetical values that may be realized upon exercise of the options immediately before the expiration of their term, assuming the specified compounded rates of appreciation of the price of ONI common stock over the term of the options. These numbers are calculated based on the rules of the Securities and Exchange Commission and do not represent an estimate of future stock price growth. Actual gains, if any, on stock option exercises and common stock holdings depend on the timing of the exercise of the option and the sale of the common stock, as well as the future performance of the common stock. The rates of appreciation assumed in this table may not be achieved and the officers may never receive the amounts reflected. This table does not take into account any change in the price of the common stock from the date of grant to the current date. The values shown are net of the option exercise price, but do not include deductions for taxes or other expenses associated with the exercise. There is no public market for ONI common stock. Prior to the end of fiscal year 2004, the most recent determination of fair market value of the ONI common stock by the ONI board of directors was \$0.26 per share on November 3, 2004. Actual gains, if any, will depend on the value of the ONI common stock on the date of the sale of the shares.

**Option grants in last fiscal year**

Name	Number of securities underlying options granted #(1)	Percent of total options granted to employees in fiscal year	Exercise price (\$/share)	Expiration date (2)	Potential realizable value at assumed annual rate of stock price appreciation for option term	
					5% (\$)	10% (\$)
Robert L. Kwolyk	500,000	37.2%	\$ 0.26	11/3/14	\$ 81,756	\$ 207,187
Peter B. Roemer	400,000	29.8%	\$ 0.26	11/3/14	\$ 65,405	\$ 165,749
Darlene M. Deptula-Hicks	200,000	14.9%	\$ 0.26	11/3/14	\$ 32,703	\$ 82,875
Ron D. Ramsey						

- (1) Represents shares of common stock issuable upon exercise of incentive and nonqualified options granted under the ONI 1997 incentive and non-statutory stock option plan during the last fiscal year. The options were granted on November 3, 2004.

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- (2) Options granted to Mr. Kwolyk, Mr. Roemer and Ms. Deptula-Hicks vest in three equal annual installments with the first third vesting on December 31, 2004. Options granted to Mr. Weatherhead vest in three equal annual installment with the first third vesting on the first anniversary of the date of grant.

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*Aggregate option exercises and fiscal year-end option values.* The following table provides information concerning stock options exercised during fiscal 2004 and stock options held at December 31, 2004 by the executive officers named in the summary compensation table.

There is no public market for ONI common stock. The value of unexercised in-the-money options at fiscal year-end, as reported in the following table, is based on \$0.26 per share, the most recent determination of fair market value prior to the end of fiscal 2004 of the ONI common stock by the ONI board of directors on November 3, 2004. Actual gains, if any, will depend on the value of the ONI common stock on the date of the sale of the shares.

**Aggregate option exercises in last fiscal year and fiscal year-end option values**

Name	Shares acquired on exercise (#)	Value realized (\$)	Number of securities underlying unexercised options at fiscal year-end		Value of unexercised in-the-money options at fiscal year-end (\$)	
			Exercisable (#)	Unexercisable (#)	Exercisable (\$)	Unexercisable (\$)
			Robert L. Kwolyk	206,650	333,350	
Peter B. Roemer	173,320	266,680				
Darlene M. Deptula-Hicks	183,326	166,674				
Ron D. Ramsey	79,996	90,005				

**Equity Compensation Plans**

The following table provides information as of December 31, 2004 regarding shares authorized for issuance under the ONI equity compensation plans, including individual compensation arrangements.

The only equity compensation plan approved by the ONI shareholders is the 1997 incentive and non-statutory stock option plan. As of December 31, 2004, ONI did not have any equity compensation plans not approved by its shareholders.

**Equity compensation plan information**

Plan category	Number of shares to be issued upon exercise of outstanding options (#)	Weighted-average exercise price of outstanding options (\$)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (#)

	(a)	(b)	(c)
Equity compensation plans approved by shareholders	2,361,660	\$ 0.65	957,172
Equity compensation plans not approved by shareholders			
<b>Total</b>	<b>2,361,660</b>	<b>\$ 0.65</b>	<b>957,172</b>

#### Agreements with Officers and Directors

ONI has agreed to pay David Hable a retainer for his services as Chairman of the board of directors. ONI expects to pay Mr. Hable \$12,000 per month for those services and, in addition, has granted Mr. Hable nonqualified stock options to purchase 55,000 shares of ONI common stock. In exchange for this retainer, Mr. Hable is expected to spend up to three days per week working with ONI in his capacity as Chairman.

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**CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS**

On August 22, 2003, ONI entered into an agreement to sell 6,201,549 shares of its Series A preferred stock for an aggregate consideration of \$8.0 million. Under the terms of the agreement, certain investors agreed to purchase an additional 2,325,582 shares of Series A preferred stock for an aggregate of \$3.0 million upon completion of an internal study and its approval by the ONI board of directors. As a result of the purchase of these ONI securities on August 22, 2003, Galen Partners IV, LP, Galen Partners International IV, LP and Ivy Healthcare Capital, L.P. became holders of more than 5% of the outstanding ONI Series A preferred stock. As contemplated by the August 22, 2003 agreement, these three investors participated in the second closing of the private placement on May 17, 2004. In that transaction, Galen Partners IV, LP purchased 1,920,858 shares of Series A preferred stock for \$2,477,907, Galen Partners International IV, LP purchased 152,592 shares for \$196,843 and Ivy Healthcare Capital, LP purchase 249,170 shares for \$321,429. In connection with this private placement, ONI and the investors also entered into a stockholders agreement, an investors rights agreement and a right of first refusal and co-sale agreement which provide the holders of Series A preferred stock with certain preemptive rights and preferences. ONI and certain of the holders of the Series A preferred stock have agreed to terminate these agreements conditioned and effective upon the closing of the merger.

During 2003, two of ONI's executives, Robert Kwolyk and Darlene Deptula-Hicks, loaned a total of \$173,000 to ONI for operating cash needs. These loans were unsecured and were repaid in full, with interest of approximately \$500 by August 2003.

ONI utilizes the services of an advertising agency owned by the brother of Robert Kwolyk, ONI's Chief Executive Officer and director. Approximately \$71,000, \$50,000, and \$29,000 were charged to operations in 2004, 2003, and 2002 respectively, for billings from the related advertising agency.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT OF ONI BEFORE THE MERGER**

The following table provides information regarding the beneficial ownership of the ONI common stock as of July 15, 2005 by:

each person known by ONI to be the beneficial owner of 5% or more of the ONI common stock;

each of ONI's executive officers named in ONI's summary compensation table, or the named executive officers;

each of ONI's directors; and

all of ONI's executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of ONI common stock subject to options, warrants and other convertible securities held by that person that are exercisable or convertible within 60 days of July 15, 2005 are deemed outstanding even if they have not actually been exercised or converted. Those shares are not deemed outstanding for the purpose of computing the percentage ownership of any other person. As of July 15, 2005, 5,929,806 shares of ONI common stock were issued and outstanding, and each share of ONI series A preferred stock was convertible into one share of ONI common stock. Unless otherwise indicated in the notes to the table, shares included in the

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Right to Acquire column represent shares issuable upon exercise of stock options that are exercisable within 60 days of July 15, 2005. Unless otherwise indicated in the notes to the table, the persons and entities named in the table have sole voting and sole investment power with respect to the shares set forth opposite the shareholder's name, subject to community property laws, where applicable.

Unless otherwise indicated in the notes to the table, the address of each shareholder listed in the table is c/o ONI Medical Systems Inc., 301 Ballardvale Street, Wilmington, Massachusetts 01887.

**Table of Contents****Beneficial Ownership of ONI Common Stock**

Name	Shares Beneficially Owned(1)			
	Number of Shares	Right to Acquire	Total	Percent
<i>Principal Shareholders</i>				
Galen Partners IV, LP (2)		7,023,357	7,023,357	54.2%
ONI Partners, LP (3)	1,266,631	124,380	1,391,011	23.0%
Sage Hill Partners (5)	737,234	233,798	971,032	15.8%
Ivy Healthcare Capital (4)		933,622	933,622	13.6%
Alvin Sherman 1993 Amended and Restated Revocable Living Trust (6)	360,000	193,798	553,798	9.0%
<i>Directors and Executive Officers</i>				
Srini Conjeevaram (7)		7,023,357	7,023,357	54.2%
Bruce F. Wesson (8)		7,023,357	7,023,357	54.2%
Robert L. Kwolyk	750,000	206,650	956,650	15.6%
Peter B. Roemer	750,000	173,320	923,320	15.1%
Darlene M. Deptula-Hicks		183,320	183,320	3.5%
Ron D. Ramsey		79,996	79,996	1.3%
David Hable		22,500	22,500	*
Douglas P. Feick		15,000	15,000	*
Stephen I. Shapiro		15,000	15,000	*
All directors and executive officers as a group (9 persons)	1,500,000	7,719,143	9,219,143	67.5%

\* Less than 1.0%

- (1) All shares will be cancelled upon completion of the merger in exchange for shares of Novoste common stock. The issuance of such shares of Novoste common stock will occur immediately after the closing of the merger.
- (2) Represents 6,993,357 shares issuable upon conversion of 6,143,646 shares of ONI series A preferred stock held by Galen Partners IV, LP, 846,749 shares held by Galen Partners International IV, LP, and 2,962 shares held by Galen Employee Fund IV, LP and 30,000 shares issuable upon exercise of stock options held by Galen Investment Advisory Group. The address of Galen Partners IV, LP is 610 Fifth Avenue, 5<sup>th</sup> Floor, New York, New York 10020.
- (3) Includes 93,620 shares issuable upon exercise of a warrant held by ONI Partners, LP, 10,760 shares issuable upon exercise of stock options held by ONI Partners, LP, as well as 20,000 shares issuable upon exercise of stock options held by Robert Cargill, the general partner of ONI Partners, LP. The address of ONI Partners, LP is 1115 North 4<sup>th</sup> Street, Longview, Texas 75601.
- (4) Represents 913,622 shares issuable upon conversion of shares of ONI series A preferred stock and 20,000 shares issuable upon exercise of stock options. The address of Ivy Healthcare Capital is One Paragon Drive, Montvale, New Jersey 07645.
- (5) The address of Sage Hill Partners is 210 Broadway, 4<sup>th</sup> Floor, Cambridge, Massachusetts 02139.
- (6) Represents shares issuable upon conversion of shares of ONI series A preferred stock. The address of the Alvin Sherman 1993 Amended and Restated Revocable Living Trust is 3000 Island Boulevard, Aventura, Florida 33160.



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- (7) Represents shares beneficially owned by Galen Partners IV, LP as described in note (2). As general partner of Galen Partners IV, LP, Galen Partners International IV, LP, and Galen Employee Fund IV, LP, Mr. Conjeevaram may be deemed to share voting and investment power for the shares held by the foregoing funds. Mr. Conjeevaram disclaims beneficial ownership of the shares held by funds affiliated with Galen Partners IV, LP except to the extent of his pecuniary interest therein.
  
- (8) Represents shares beneficially owned by Galen Partners IV, LP as described in note (2). As managing director of Galen Partners IV, LP, Galen Partners International IV, LP, and Galen Employee Fund IV, LP, Mr. Wesson may be deemed to share voting and investment power for the shares held by the foregoing funds. Mr. Wesson disclaims beneficial ownership of the shares held by funds affiliated with Galen Partners IV, LP except to the extent of his pecuniary interest therein.

**Table of Contents****Beneficial Ownership of ONI Series A Preferred Stock**

ONI has one series of preferred stock outstanding, Series A preferred stock. As of July 15, 2005, 9,147,285 shares of Series A preferred stock were issued and outstanding. The following table provides information regarding the beneficial ownership of the ONI Series A preferred stock as of July 15, 2005 by:

each person known by ONI to be the beneficial owner of 5% or more of the ONI Series A preferred stock;

each of ONI's named executive officers;

each of ONI's directors; and

all of ONI's executive officers and directors as a group.

<u>Name</u>	<u>Shares Beneficially Owned(1)</u>	
	<u>Number of Shares</u>	<u>Percent</u>
<i>Principal Shareholders</i>		
Galen Partners IV, LP (2)	6,993,357	76.5%
Ivy Healthcare Capital	913,622	10.0%
<i>Directors and Executive Officers</i>		
Srini Conjeevaram (3)	6,993,357	76.5%
Bruce F. Wesson (4)	6,993,357	76.5%
Robert L. Kwolyk		
Peter B. Roemer		
Darlene M. Deptula-Hicks		
Ron D. Ramsey		
David Hable		
Douglas P. Feick		
Stephen I. Shapiro		
Randy L. Weatherhead		
All directors and executive officers as a group (10 persons)	6,993,357	76.5%

- (1) All shares will be cancelled upon completion of the merger in exchange for shares of Novoste common stock. The issuance of such shares of Novoste common stock will occur immediately after the closing of the merger.
- (2) Represents 6,143,646 shares held by Galen Partners IV, LP, 846,749 shares held by Galen Partners International IV, LP, and 2,962 shares held by Galen Employee Fund IV, LP.
- (3) Represents shares beneficially owned by Galen Partners IV, LP as described in note (2). As general partner of Galen Partners IV, LP, Galen Partners International IV, LP, and Galen Employee Fund IV, LP, Mr. Conjeevaram may be deemed to share voting and investment

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power for the shares held by the foregoing funds. Mr. Conjeevaram disclaims beneficial ownership of the shares held by funds affiliated with Galen Partners IV, LP except to the extent of his pecuniary interest therein.

- (4) Represents shares beneficially owned by Galen Partners IV, LP as described in note (2). As managing director of Galen Partners IV, LP, Galen Partners International IV, LP, and Galen Employee Fund IV, LP, Mr. Wesson may be deemed to share voting and investment power for the shares held by the foregoing funds. Mr. Wesson disclaims beneficial ownership of the shares held by funds affiliated with Galen Partners IV, LP except to the extent of his pecuniary interest therein.

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**MARKET PRICE OF AND DIVIDENDS ON THE ONI COMMON EQUITY AND RELATED SHAREHOLDER MATTERS**

There is currently no public market for ONI common stock. The ONI shares of common stock issued are restricted securities, which means they were originally sold in offerings that were not subject to a registration statement filed with the SEC. These restricted shares may be resold only through registration under the Securities Act or under an available exemption from registration, such as that provided in Rule 144. The ONI certificate of incorporation provides for one series of preferred stock. Upon completion of the merger, all outstanding shares of ONI common stock and ONI Series A preferred stock will convert automatically into the right to receive shares of Novoste common stock in accordance with the applicable exchange ratio provided by the merger agreement. As of June 30, 2005, there were 61 holders of 5,929,806 outstanding shares of ONI common stock and 13 holders of 9,147,285 outstanding shares of ONI series A convertible preferred stock.

As of June 30, 2005, there were outstanding options to purchase a total of 2,526,660 shares of ONI common stock at a weighted average exercise price of \$0.62 per share, warrants to purchase a total of 618,280 shares of ONI common stock at a weighted average exercise price of \$1.29 per share, and warrants to purchase a total of 2,325,581 shares of ONI Series A preferred stock at a weighted average exercise price of \$1.29 per share. The merger agreement provides that upon completion of the merger, each ONI option and warrant will be converted into Novoste stock options and warrants based on the exchange ratio in the merger agreement. To the extent any of these options or warrants are exercised, there will be dilution to the current holders of Novoste common stock.

ONI has never declared or paid any cash dividends on its capital stock. ONI anticipates that it will retain all future earnings, if any, to support operations and to finance the growth and development of its business and therefore does not expect to pay cash dividends between now and the closing of the merger. The dividend policy following the merger will be determined by the combined company's board of directors.

**Table of Contents****SELECTED HISTORICAL FINANCIAL DATA OF ONI**

The selected consolidated 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 ONI's audited financial statements included in this proxy statement. The selected consolidated financial data shown below for the fiscal quarters ended March 31, 2005 and 2004, and as of March 31, 2005, have been taken or derived from ONI's unaudited financial statements included in this proxy statement. In the opinion of ONI's management, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the results of the interim periods. Operating results for the three months ended March 31, 2005 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2005. The selected consolidated financial data shown below for the fiscal years ended December 31, 2001 and 2000, and as of December 31, 2002, 2001 and 2000, have been derived from ONI's financial statements for those years, which are not included in this proxy statement. The selected consolidated financial data shown below should be read in conjunction with the financial statements and related notes of ONI and with ONI Management's Discussion and Analysis of Financial Condition and Results of Operations, which are included elsewhere in this proxy statement.

	Three Months Ended March 31		Year Ended December 31				
	2005	2004	2004	2003	2002	2001	2000
(In thousands, except per share amounts)							
<b>Consolidated Statement of Operations Data:</b>							
Total revenue	\$ 2,629	\$ 655	\$ 8,887	\$ 8,297	\$ 6,276	\$ 725	\$
Total cost of revenue	2,125	758	7,826	5,761	4,752	1,358	
Gross profit (loss)	504	(103)	1,061	2,536	1,524	(633)	
Research and development	602	466	1,843	1,783	2,328	1,766	1,534
Sales and marketing	977	963	3,392	2,291	1,894	1,300	234
General and administrative	515	443	1,822	1,314	1,255	1,242	936
Loss from operations	(1,590)	(1,975)	(5,996)	(2,852)	(3,953)	(4,941)	(2,704)
Other income (expense)		25	(4)	(206)	(188)	67	90
Net loss	\$ (1,590)	\$ (1,950)	\$ (6,000)	\$ (3,058)	\$ (4,141)	\$ (4,874)	\$ (2,614)
Basic and diluted net loss per share	\$ (0.27)	\$ (0.33)	\$ (1.01)	\$ (0.90)	\$ (2.06)	\$ (4.81)	\$ (2.86)
Weighted average shares outstanding	5,930	5,930	5,930	3,408	2,013	1,014	914

	At March 31,	At December 31				
	2005	2004	2003	2002	2001	2000
(In thousands)						
<b>Consolidated Balance Sheet Data:</b>						
Working capital (deficit)	\$ (1,794)	\$ 153	\$ 2,844	\$ (1,064)	\$ (290)	\$ (100)
Total assets	7,064	7,829	6,906	5,113	3,667	3,113
Long-term liabilities	660	397				
Redeemable convertible preferred stock	11,800	11,800	8,500			

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Accumulated deficit	(25,397)	(23,807)	(17,806)	(14,552)	(10,411)	(5,537)
Total shareholders' equity (deficit)	(12,438)	(10,848)	(4,646)	88	758	552

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**Table of Contents****ONI MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The forward-looking statements in this discussion and analysis are made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended. ONI's results of operations and financial condition have varied and may in the future vary significantly depending on a number of factors. Statements in this discussion and analysis which are not strictly historical statements, including statements regarding management's expectations regarding ONI's revenue opportunities, international expansion, trends in revenues and expenses, product development efforts and general business plans and strategies, 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, or the negative of these words or comparable words. The factors listed under Risk Factors, beginning on page 13 of this proxy statement, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this discussion and analysis. Such factors, among others, may have a material adverse effect upon ONI's business, financial condition and results of operations. ONI undertakes no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future global events or otherwise. Accordingly, you are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made.

The following management's discussion and analysis of financial condition and results of operations is organized as follows:

*Overview.* This section provides a general description of ONI, as well as recent developments and events that ONI believes are important in understanding its results of operations and financial condition and to anticipate future trends.

*Results of Operations.* This section provides an analysis of ONI's results of operations for the three months ended March 31, 2005 and March 31, 2004, and for the fiscal years ended December 31, 2004, December 31, 2003 and December 31, 2002.

*Liquidity and Capital Resources.* This section provides an analysis of ONI's cash flows for the three months ended March 31, 2005 and for the fiscal years ended December 31, 2004 and December 31, 2003, as well as a discussion of recent financing arrangements.

*Critical Accounting Policies.* This section discusses the critical accounting policies that ONI considers important to an understanding of its financial condition and results of operations, and that required significant judgment and estimates on the part of management in application. ONI's significant accounting policies, including the critical accounting policies discussed in this section, are summarized in the notes to the accompanying financial statements of ONI.

*New Accounting Pronouncements.* This section discusses newly issued accounting standards and the impact that ONI expects they may have on its financial statements.

**Overview**

Founded in 1997, ONI develops, manufactures and markets dedicated-purpose magnetic resonance imaging, or MRI, systems offering high-field performance at a low cost. ONI's first product, the OrthOne, is a compact, high-field (1.0 Tesla), MRI extremity system that provides images of the hands, wrists, elbows, knees, ankles and feet. The OrthOne system provides images that are superior in quality to those of low-field extremity systems and similar to those of high-field, whole-body systems installed in diagnostic imaging centers or hospitals, but for approximately one-third of the cost of a new whole-body system and a fraction of the size.

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ONI obtained clearance from the Food and Drug Administration, or the FDA, to market the OrthOne system in August 2000 and began to generate revenue from sales in the fourth quarter of 2001. In June 2004, ONI received CE mark approval allowing it to sell the OrthOne system in certain countries in Europe. ONI is in the process of developing a second dedicated-purpose high-field MRI system. ONI's current product goal is to



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address the needs of additional emerging market applications for high-field, dedicated-purpose MRI systems. ONI expects to introduce the new MRI system by the end of 2007.

ONI's revenue includes system revenue, service revenue and other revenue. System revenue is generated through the sale of OrthOne systems. Service revenue is generated from service maintenance contracts, time and material services and spare parts sales. Other revenue consists of revenue received from providing turnkey construction services to customers. On a limited basis ONI acts as the general contractor to prepare the customer site for installation of the OrthOne system and sub-contracts the site preparation to third parties. ONI's revenue is concentrated in a relatively small number of transactions. The time from the receipt of a customer order to shipment of the order varies widely but averages between four and six months.

In the U.S. market, ONI sells and services the OrthOne system through its direct sales and direct field service organizations. ONI typically warrants its product to customers for a period of one year from the date of installation. After the warranty period, ONI's customers typically enter into single or multi-year service maintenance agreements. In Europe, ONI sells the OrthOne system through distributors. ONI's distributors assume the responsibility for system installation, customer training and system warranty, and receive the benefit of any revenue from customer service maintenance contracts. International revenue accounted for 25.1% of total revenue for the three months ended March 31, 2005 and 6.5% of total revenue in the year ended December 31, 2004. ONI expects international revenue to grow in total dollars in 2005 as it executes on its business plan, which includes expansion in international markets.

ONI has incurred ongoing operating losses and has generated negative cash flow from operations since inception. ONI has financed its operations primarily through the private sale of shares of its stock.

The audit report issued by Ernst & Young LLP, ONI's independent registered public accounting firm, regarding ONI's 2004 financial statements included an explanatory paragraph expressing substantial doubt about ONI's ability to continue as a going concern based on conditions existing at December 31, 2004 and as of the date of its audit report.

Under the terms of the merger agreement, ONI will become a wholly owned subsidiary of Novoste, and the combined company will be renamed ONI Medical Systems, Inc. The existing management of ONI is expected to become the management of the combined company. The board of directors of the combined company will include a majority of independent directors. For accounting purposes, the merger will be treated as a reverse merger and ONI will be treated as the acquirer. The merger is expected to generate approximately \$9,500,000 in net cash assets, which is in addition to the \$3,000,000 received in May 2005 from Novoste in the form of an unsecured loan. Upon completion of the merger, the loan will be extinguished. The closing of the merger is expected to occur during the third quarter of 2005, subject to approval by the stockholders of Novoste.

As a privately held company, ONI has not been subject to the periodic reporting or other requirements of the Securities Exchange Act of 1934, as amended. Accordingly, ONI's financial statements do not reflect the significant accounting, legal and other expenses that the combined company will face as a public company. Although ONI is currently unable to estimate these costs with any degree of certainty, it expects that these expenses will be substantial in relation to ONI's revenues and will adversely affect its results of operations.

**Table of Contents****Results of Operations**

The following table provides certain consolidated statements of operations data for the periods indicated as a percentage of total revenue.

	Three months				
	ended March 31		Years ended December 31		
	2005	2004	2004	2003	2002
Revenues:					
System revenue	85.8%	87.3%	93.4%	99.4%	100%
Service revenue	8.2	12.7	6.6	0.6	0.0
Other revenue	6.0	0.0	0.0	0.0	0.0
Total revenue	100.0	100.0	100.0	100.0	100.0
Cost of revenues:					
Cost of system revenue	63.4	69.2	80.2	68.9	75.7
Cost of service revenue	11.4	46.4	7.9	0.5	0.0
Cost of other revenue	6.0	0.0	0.0	0.0	0.0
Total cost of sales	80.8	115.6	88.1	69.4	75.7
Research and development	22.9	71.1	20.7	21.5	37.1
Sales and marketing	37.2	147.0	38.2	27.6	30.2
General and administrative	19.6	67.8	20.5	15.9	20.0
Total operating expenses	79.7	285.9	79.4	65.0	87.3
Loss from operations	(60.5)	(301.5)	(67.5)	(34.4)	(63.0)
Total other expense	(0.0)	3.8	(0.0)	(2.5)	(3.0)
Net loss	(60.5)%	(297.7)%	(67.5)%	(36.9)%	(66.0)%

**Comparison of the three months ended March 31, 2005 and 2004**

The unaudited interim financial information of ONI contained in this discussion and analysis has been prepared on the same basis as ONI's audited financial statements and, in the opinion of ONI's management, includes all adjustments, consisting of only normal recurring adjustments, that ONI considers necessary to present fairly the information when read together with ONI's audited financial statements and the related notes appearing elsewhere in this proxy statement. ONI believes that future quarterly fluctuations in its results of operations are likely and therefore does not believe that its operating results in any quarter or quarters should be relied upon as an accurate indicator of its future performance.

*Revenues.* System revenue increased by \$1,684,000 or 294.4%, to \$2,256,000 in the three months ended March 31, 2005 from \$572,000 in the three months ended March 31, 2004. This increase is primarily attributable to the recognition of revenue for six systems during the quarter ended March 31, 2005 and one system during the quarter ended March 31, 2004. Two of the systems for which ONI recognized revenue during the three months ended March 31, 2005 were shipped to customers in previous periods but were subject to customer acceptance, which was received during the first quarter of 2005. The revenue recognized per system decreased during the three months ended March 31, 2005 from the three months ended March 31, 2004 due to the timing of revenue recognition relating to undelivered elements. International revenue accounted for 25.1% of total revenue in the three months ended March 31, 2005 and 0% in the comparable period in 2004. Service revenue increased by \$133,000, or 160.2%, to \$216,000 in the three months ended March 31, 2005 from \$83,000 in the three months ended March 31, 2004. This increase is primarily attributable to an increase in the number of systems coming off warranty and commencing annual service maintenance contracts. ONI expects service revenue to increase in total dollars in 2005 as systems continue to come off warranty and customers purchase service maintenance contracts.

In the three months ended March 31, 2005, ONI also generated \$157,000 in other revenue from providing construction services to a customer as part of a system sale. ONI expects to offer these construction services on a very limited basis and therefore does not expect these services to generate other revenue on a regular basis.

*Cost of Revenue.* Cost of system revenue consists primarily of material, labor and overhead, the cost of product warranty, installation, training and other cost of sales. Cost of system revenue increased by \$1,215,000,

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or 268.2%, to \$1,668,000 in the three months ended March 31, 2005 from \$453,000 in the three months ended March 31, 2004. As a percentage of system revenue, cost of system revenue was 73.9% in the three months ended March 31, 2005 and 79.2% in the comparable period in 2004. Cost of system revenue decreased as a percentage of system revenue in the 2005 period primarily as a result of increased system shipments from the low product shipments in the 2004 period.

Cost of service revenue consists primarily of the material, labor and overhead and part repair costs relating to field service, as well as the travel expenses of service personnel. Cost of service revenue decreased by \$4,000, or 1.3%, to \$300,000 in the three months ended March 31, 2005 from \$304,000 in the three months ended March 31, 2004. As a percentage of service revenue, cost of service revenue was 138.9% in the three months ended March 31, 2005 and 366.3% in the comparable period in 2004. In both the 2005 and 2004 periods, cost of service revenue was high in relation to service revenue due to the limited number of installed systems relative to the expenses ONI incurred to offer field service at customer sites across the United States. The service organization is operating at a negative gross margin primarily due to the costs associated with establishing and maintaining the base infrastructure required to support a domestic service organization. ONI expects that, to the extent its installed customer base grows, cost of service revenue will decline as a percentage of service revenue.

*Research and Development.* Research and development expenses include primarily the costs of ONI's research team, engineers and consultants as well as research and development materials and depreciation on research and development assets. Research and development expenses increased by \$136,000, or 29.2%, to \$602,000 in the three months ended March 31, 2005 from \$466,000 in the three months ended March 31, 2004. We began development of a new dedicated-purpose MRI system in late 2004, and this increase is primarily attributable to costs associated with development of the magnet for the new MRI system. ONI anticipates that in future periods its research and development expenses will increase significantly in total dollars as a result of executing its product development plans.

*Sales and Marketing.* Sales and marketing expenses represent the cost of ONI's direct sales force, sales and marketing management and sales and marketing programs, including trade show expenses. Sales and marketing expenses increased by \$14,000, or 1.5%, to \$977,000 in the three months ended March 31, 2005 from \$963,000 in the three months ended March 31, 2004. This increase is primarily attributable to a \$123,000 increase in trade show expense, an \$80,000 increase in commission expense, and a \$24,000 increase in sales-related expenses, offset by decreases of \$115,000 in marketing materials, advertising and promotions and \$99,000 in recruiting expenses. ONI anticipates that in future periods its sales and marketing expenses will continue to increase in total dollars as a result of its implementing its business strategy, which includes increasing the size of its direct sales force and expanded marketing personnel and programs.

*General and Administrative.* General and administrative expenses include finance and accounting and general management personnel, legal and accounting fees, business insurances, board of director fees, and other general and administrative expenses. General and administrative expenses increased by \$72,000, or 16.3%, to \$515,000 in the three months ended March 31, 2005 from \$443,000 in the three months ended March 31, 2004. This increase is primarily attributable to increases in employee compensation of \$92,000 and legal and accounting fees of \$8,000, offset in part by a \$30,000 reduction in bad debt expense. ONI anticipates that in future periods its general and administrative expenses will continue to increase in total dollars expended primarily as a result of the additional costs associated with being a public company.

*Other Income and Expense.* Other income and expense consists primarily of foreign currency gains or losses, interest earned on short-term investments and miscellaneous interest or other income or expense. Total other income was \$0 for the three months ended March 31, 2005 and \$25,000 for the three months ended March 31, 2004. This decrease in other income is primarily attributable to an increase in foreign exchange expense on the settlement of inventory purchases from the United Kingdom and increases in interest expense and franchise tax fees.

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*Net Loss.* ONI's net loss decreased by \$360,000, or 18.5%, to \$1,590,000 in the three months ended March 31, 2005 from \$1,950,000 in the three months ended March 31, 2004.

*Backlog.* ONI's backlog as of March 31, 2005 totaled approximately \$7,167,000 compared to \$3,055,000 as of March 31, 2004. Of these amounts, approximately \$780,000 and \$393,000 had been paid to ONI as customer advances at March 31, 2005 and 2004, respectively. It is expected that approximately 75% of the existing backlog at March 31, 2005 will be filled within the current fiscal year. ONI's contracts generally provide that if a customer cancels an order, the customer's initial down payment for the system is nonrefundable. Backlog as of any particular period should not be relied upon as indicative of ONI's net revenues for any future period.

## **Comparison of the fiscal years ended December 31, 2004 and 2003**

*Revenues.* System revenue increased by \$58,000, or 0.7%, to \$8,303,000 in the year ended December 31, 2004 from \$8,245,000 in the year ended December 31, 2003. This increase is primarily attributable to the shipment of two additional systems in 2004 from 2003, offset by deferral of revenue of approximately \$372,000 for undelivered elements of several customer shipments and \$258,000 for non-standard warranty. The revenue recognized per system has decreased during the year ended December 31, 2004 from the year ended December 31, 2003 due to the timing of revenue recognition relating to undelivered elements and lower selling prices on international orders. Average selling prices for 2004 were comparable to those in 2003.

Service revenue increased by \$532,000 to \$584,000 in the year ended December 31, 2004 from \$52,000 in the year ended December 31, 2003. This increase is primarily attributable to an increase in the number of systems coming off warranty and commencing annual service maintenance contracts.

*Cost of Revenue.* Cost of system revenue increased by \$1,410,000, or 24.7%, to \$7,125,000 in the year ended December 31, 2004 from \$5,715,000 in the year ended December 31, 2003. As a percentage of system revenue, cost of system revenue was 85.8% in the year ended December 31, 2004 and 69.3% in the year ended December 31, 2003. The primary factors that contributed to this increase in cost of system revenue include a \$977,000 increase in material and overhead costs, a \$199,000 increase in customer promotion costs, a \$104,000 increase in repair and rework costs on subassemblies and a \$72,000 increase in net realizable value adjustments on company-owned inventory at a customer site, all of which contributed to a decrease in gross margin year over year. We are not able to cover all of these costs through higher unit selling prices year over year.

Cost of service revenue increased by \$656,000 to approximately \$702,000 in the year ended December 31, 2004 from approximately \$46,000 in the year ended December 31, 2003. As a percentage of service revenue, cost of service revenue was 120.2% in the year ended December 31, 2004 and 87.5% in the year ended December 31, 2003. The primary factor that contributed to this increase in cost of service revenue in total dollars is an increase in service maintenance costs to support systems coming off warranty and commencing annual service maintenance agreements. The service organization operated at a negative gross margin due primarily to costs associated with establishing and maintaining the base infrastructure required to support a domestic service organization.

*Research and Development.* Research and development expenses increased by \$60,000, or 3.4%, to \$1,843,000 in the year ended December 31, 2004 from \$1,783,000 in the year ended December 31, 2003. This increase is primarily attributable to expenses incurred in connection with new product development. We commenced development of a new MRI system in late 2004.

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*Sales and Marketing.* Sales and marketing expenses increased by \$1,101,000, or 48.1%, to \$3,392,000 in the year ended December 31, 2004 from \$2,291,000 in the year ended December 31, 2003. This increase is primarily attributable to a \$492,000 increase in employee compensation, including new sales and marketing management personnel and higher sales commissions, a \$341,000 increase in trade show expenses, as well as increases in travel expenses, marketing programs and general advertising.

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*General and Administrative.* General and administrative expenses increased by \$508,000, or 38.7%, to \$1,822,000 in the year ended December 31, 2004 from \$1,314,000 in the year ended December 31, 2003. This increase is primarily attributable to a \$257,000 increase in compensation for employees and directors, including employee bonuses, a \$189,000 increase in outside legal and accounting fees and increased travel expenses.

*Other Income and Expense.* Total other expense decreased to \$4,000 for the year ended December 31, 2004 from \$206,000 for the year ended December 31, 2003. The decrease in other expense is primarily attributable to a \$175,000 reduction in foreign currency losses arising from the settlement of inventory purchases, as well as a reduction in interest expense and an increase in interest income.

*Net Loss.* ONI's net loss increased \$2,942,000, or 96.2%, to \$6,000,000 in the year ended December 31, 2004 from \$3,058,000 in the year ended December 31, 2003. This increase in net loss is largely attributable to an increase in product costs and expansion of sales and marketing activities.

## **Comparison of the fiscal years ended December 31, 2003 and 2002**

*Revenues.* System revenue increased by \$1,969,000, or 31.4%, to \$8,245,000 in the year ended December 31, 2003 from \$6,276,000 in the year ended December 31, 2002. The increase was primarily attributable to the shipment of four additional systems in the year ended December 31, 2003 from the year ended December 31, 2002, as well as an increase in the average selling price of approximately 3.2% during the same periods.

Service revenue increased to \$52,000 in the year ended December 31, 2003 from \$0 in the year ended December 31, 2002. The increase is primarily attributable to systems coming off warranty and commencing annual service maintenance contracts.

*Cost of Revenue.* Cost of system revenue increased by \$963,000, or 20.3%, to \$5,715,000 in the year ended December 31, 2003 from \$4,752,000 in the year ended December 31, 2002. As a percentage of system revenue, cost of system revenue was 69.3% in the year ended December 31, 2003 and 75.7% in the year ended December 31, 2002. The primary factor that contributed to this dollar increase in cost of system revenue was a \$668,000 increase in material and overhead costs associated primarily with the increased number of systems shipped and a \$269,000 increase in customer promotional costs. The increase in gross margin from the year ended December 31, 2002 to the year ended December 31, 2003 is primarily due to an increase in average selling price and a decrease in material and overhead costs.

Cost of service revenue was \$46,000 in the year ended December 31, 2003 and \$0 in the year ended December 31, 2002. As a percentage of service revenue, cost of service revenue was 87.5% in the year ended December 31, 2003. The primary factor that contributed to this increase in cost of service revenue was an increase in service maintenance costs to support systems coming off warranty and commencing annual service maintenance agreements. The service organization operated at a negative gross margin due primarily to costs associated with establishing and maintaining the base infrastructure required to support a domestic service organization.

*Research and Development.* Research and development expenses decreased by \$545,000, or 23.4%, to \$1,783,000 in the year ended December 31, 2003 from \$2,328,000 in the year ended December 31, 2002. This decrease is primarily attributable to the consolidation of research activities into one location.

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*Sales and Marketing.* Sales and marketing expenses increased by \$397,000, or 21.0%, to \$2,291,000 in the year ended December 31, 2003 from \$1,894,000 in the year ended December 31, 2002. This increase is primarily attributable to a \$142,000 increase in employee compensation, largely due to commission expense attributable to an increase in orders and shipments and to increased headcount, a \$149,000 increase in marketing promotions and marketing materials, and a \$52,000 increase in consulting expense.

*General and Administrative.* General and administrative expenses increased by \$59,000, or 4.7%, to \$1,314,000 in the year ended December 31, 2003 from \$1,255,000 in the year ended December 31, 2002. The increase is primarily attributable to an increase in legal fees and compensation expense, offset in part by a reduction in rent expense as the lease on ONI's former facility ended.



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*Other Income and Expense.* Total other expense increased by \$18,000, or 9.6%, to \$206,000 for the year ended December 31, 2003 from \$188,000 for the year ended December 31, 2002. This increase in other expense is primarily attributable to a \$46,000 increase in foreign exchange losses, offset in part by a reduction in interest expense and an increase in interest income.

*Net Loss.* The net loss decreased by \$1,083,000, or 26.2%, to \$3,058,000 in the year ended December 31, 2003 from \$4,141,000 in the year ended December 31, 2002.

## **Liquidity and Capital Resources**

ONI has financed its operations since inception primarily through the private sale of shares of its stock. During 2003 and 2004, ONI received net proceeds of approximately \$7,109,000 and \$3,094,000, respectively, from the sale of equity securities.

The audit report issued by Ernst & Young LLP, ONI's independent registered public accounting firm, regarding ONI's 2004 financial statements included an explanatory paragraph expressing substantial doubt about ONI's ability to continue as a going concern based on conditions existing as of December 31, 2004 and as of the date of its audit report.

At March 31, 2005, ONI had approximately \$450,000 in cash and cash equivalents. ONI also had a \$1,000,000 secured revolving line of credit from a commercial bank. The principal amount of any outstanding revolving advances bears interest at the bank's prime rate plus one percent, and purchase order advances bear interest at the bank's prime rate plus three percent. Under the provisions of the revolving line of credit agreement, ONI is required to maintain compliance with an adjusted quick ratio financial covenant. At March 31, 2005, there were no borrowings on the line. ONI was not in compliance with the covenant and, as a result, the line of credit was not available for borrowing at that time.

On May 18, 2005, ONI entered into the merger agreement with Novoste. As part of the terms of the merger agreement, Novoste provided ONI with an 18-month, senior unsecured loan in the principal amount of \$3,000,000, bearing interest at a rate of 8% per year. Under certain circumstances in which the merger agreement is terminated, the repayment of the loan will accelerate at the time of termination. In connection with the loan, ONI granted to Novoste a warrant to purchase up to an aggregate of 2,325,581 shares of ONI Series A preferred stock. Novoste may exercise the warrant either by paying cash or by surrendering some or all of the promissory note. Under certain circumstances in which the merger agreement is terminated, Novoste must surrender the warrant if it has not yet been exercised at the time of termination. Upon the closing of the merger agreement, the note will become a component of the net cash assets of Novoste and both the note and the warrant will be extinguished.

ONI's future capital requirements will depend upon many factors, including speed of market penetration of the OrthOne system, ONI's ability to bring new products to market on a timely basis, market acceptance of its products, regulatory approvals, competing technological and market developments, effective new product commercialization, marketing and sales activities, cost associated with being a public company and other arrangements.

ONI expects to continue to incur net losses and negative cash flows for at least the foreseeable future. Based upon its current plans, ONI believes that its existing capital resources, and the approximately \$12,500,000 in net cash assets expected with the merger with Novoste, together with any cash generated from operations, will be sufficient to meet ONI's operating expenses and capital requirements for the foreseeable future.

However, changes in ONI's business strategy, product development, market adoption, sales and marketing plans or other events affecting ONI's operating plans and expenses may result in earlier expenditure of existing cash resources. If this occurs, ONI's ability to meet its cash obligations as they become due and payable will depend on its ability to sell securities or borrow funds. ONI may not be successful in raising any necessary funds on acceptable terms, or at all.

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*Operating Activities.* During the three months ended March 31, 2005, operating activities used approximately \$570,000 of cash. Net cash used by operating activities in the three months ended March 31, 2005 primarily reflects a \$1,590,000 operating loss, a \$757,000 increase in other assets, which includes ONI inventory at a customer site, a long-term receivable and costs associated with the merger transaction, a \$537,000 increase in inventory to meet ONI's manufacturing plan and scale up of the business and a \$371,000 decrease in deferred revenue offset by a \$1,258,000 reduction in accounts receivable as ONI collected accounts receivable during the first quarter from a strong fourth quarter of shipments, a \$589,000 increase in accounts payable due in part to the increase in inventory to scale up the business, and a \$330,000 increase in long-term deferred revenue due to the installation of a system in Europe with extended payment terms. During the three months ended March 31, 2004, operating activities used approximately \$1,791,000 of cash. Net cash used by operating activities in the three months ended March 31, 2004 primarily reflects a \$1,950,000 operating loss, which was reflective of shipping only one system in the quarter, a \$787,000 increase in inventory to meet ONI's manufacturing plan and scale up of business and a \$184,000 decrease in accrued expenses, offset by a \$640,000 reduction in accounts receivable due to collection of accounts receivable during the first quarter from a strong fourth quarter of shipments, a \$262,000 increase in accounts payable and a \$167,000 increase in customer deposits.

During fiscal 2004, operating activities used approximately \$5,239,000 of cash. Net cash used by operating activities in 2004 primarily reflects a \$6,000,000 operating loss, a \$1,636,000 increase in accounts receivable primarily from strong December shipments that were unpaid at year end, \$1,046,000 relating to new rights under a reseller agreement and a \$475,000 increase in inventory to meet ONI's manufacturing plan and scale up of business, offset by a \$1,196,000 increase in deferred revenue due to the timing of revenue recognition relating to undelivered elements, an \$882,000 increase in accounts payable, an \$850,000 increase in obligations under a reseller agreement, a \$592,000 increase in accrued expenses and a \$306,000 increase in customer deposits.

During fiscal 2003, operating activities used approximately \$2,274,000 of cash. Net cash used by operating activities in 2003 primarily reflects a \$3,058,000 operating loss, a \$428,000 decrease in accounts payable, a \$277,000 decrease in customer deposits and a \$160,000 decrease in accrued expenses, offset by a \$1,175,000 decrease in inventory and a \$381,000 decrease in deposits and other assets.

During fiscal 2002, operating activities used approximately \$2,938,000 of cash. Net cash used by operating activities in 2002 primarily reflects a \$4,141,000 operating loss, a \$769,000 increase in accounts receivable and a \$739,000 increase in inventory, offset by a \$965,000 increase in accounts payable, a \$638,000 increase in deferred revenue, a \$521,000 increase in customer deposits and a \$346,000 decrease in prepaid expenses and other current assets.

*Investing Activities.* ONI's investing activities used net cash of \$19,000 in the three months ended March 31, 2005, \$69,000 in the three months ended March 31, 2004, \$281,000 in the year ended December 31, 2004, \$602,000 in the year ended December 31, 2003 and \$221,000 in the year ended December 31, 2002. These activities consisted of investments in property, plant and equipment. In the year ended December 31, 2004, ONI also had a \$50,000 increase in restricted cash.

*Financing Activities.* No cash was provided by or used in financing activities in the three months ended March 31, 2005 or March 31, 2004. ONI's financing activities provided net cash of \$3,094,000 in the year ended December 31, 2004, \$5,815,000 in the year ended December 31, 2003 and \$3,381,000 in the year ended December 31, 2002. ONI's financing activities during these periods consisted primarily of the sale of shares of preferred stock. In the year ended December 31, 2003, ONI also used \$500,000 to repay short-term debt and \$794,000 to repurchase shares of common stock.

**Off-balance Sheet Arrangements**

At December 31, 2004, ONI had no off-balance sheet arrangements.

**Table of Contents****Contractual Obligations**

ONI has a five-year lease agreement for office space under an operating lease. The term of the lease expires in 2009. ONI has one five-year renewal option.

In March 2001, ONI and GE Medical Systems entered into an agreement, pursuant to which GE Medical Systems agreed to manufacture and supply ONI with the magnet used in the OrthOne system. The amount shown in the following table with respect to the GE Medical Systems agreement represents ONI's obligations with respect to magnet orders pending as of December 31, 2004. Although ONI has no contractual commitment to place further orders, it expects to do so. The table does not reflect magnet orders placed after December 31, 2004. The table also assumes that orders pending as of December 31, 2004 will be fulfilled and paid for in 2005.

In August 2004, ONI and Cedera Software Corp. entered into a three-year, non-cancelable value-added reseller agreement, pursuant to which Cedera agreed to supply software for incorporation into ONI's products. The agreement contains minimum payment obligations requiring ONI to pay an aggregate of \$1,320,000 over the term of the agreement. ONI may purchase additional software licenses at prices specified in the agreement.

As of December 31, 2004, ONI had contractual obligations as follows:

<u>Contractual Obligations</u>	<u>Payments due by period</u>				
	<u>Total</u>	<u>2005</u>	<u>2006-2007</u>	<u>2008-2009</u>	<u>After 2009</u>
Operating lease obligations	\$ 1,129,708	\$ 240,456	\$ 484,701	\$ 404,551	
Purchase obligations:					
Value-added reseller agreement	947,000	472,000	475,000		
GE Medical agreement	4,037,660	4,037,660			
Total	\$ 6,114,368	\$ 4,750,116	\$ 959,701	\$ 404,551	

**Critical Accounting Policies**

This discussion and analysis of ONI's financial condition and results of operations are based on its financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires ONI to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. ONI reviews its estimates on a regular basis. ONI bases its estimates on historical experience and on various other assumptions that ONI believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities. Some of the more significant estimates include revenue recognition, inventory valuation, useful lives of property and equipment, accrued liabilities including warranty accruals and other allowances. Actual results may differ from these estimates under different assumptions or conditions. While ONI's significant accounting policies are described in more detail in note 2 to its financial statements, ONI believes the following accounting policies to be critical to the judgment and estimates used in the preparation of its financial statements.

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*Revenue Recognition.* ONI's revenue recognition policy involves significant judgment by management. Revenue is generally recognized when products are delivered or services are performed. When the terms of the sale include customer acceptance provisions, and compliance with those provisions cannot be demonstrated, revenues are deferred and not recognized until such acceptance occurs. As described in detail below, ONI considers all relevant facts and circumstances in determining when to recognize revenue, including contractual obligations to the customer, the customer's post delivery acceptance provisions, if any, and the installation process.

For revenue arrangements prior to July 1, 2003, ONI generally recognized the full sale price at the time of shipment to the customer. The cost of system installation at the customer's site was accrued at the time of

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shipment. In addition, the standard and non-standard warranties were accrued at the time of shipment. ONI recognized the full sales price at the time of shipment, as management believed that the customer's post delivery provisions and installation process were established to be routine and commercially inconsequential. Also, customer payment terms typically provided that the majority of the purchase price was payable upon delivery.

In November 2002, the Financial Accounting Standards Board's Emerging Issues Task Force reached a consensus on Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, also known as EITF 00-21. This issue addresses determination of whether an arrangement involving more than one deliverable contains more than one unit of accounting and how the arrangement consideration should be measured and allocated to the separate units of accounting. EITF 00-21 became effective for revenue arrangements entered into in periods beginning after June 15, 2003. For revenue arrangements occurring on or after July 1, 2003, ONI has revised its revenue recognition policy to comply with the provisions of EITF 00-21.

ONI revenue transactions generally include sales of systems under multiple element arrangements. ONI considers the guidance in EITF 00-21 and Securities and Exchange Commission, or the SEC, Staff Accounting Bulletin No. 104, *Revenue Recognition*, also known as SAB 104. Revenue under these arrangements is allocated to each element, except systems, based upon its estimated fair market value. The amount of revenue allocated to systems is calculated on a residual method. Under this method, the total value of the arrangement is allocated first to the undelivered elements, with the residual amount being allocated to system revenue. The value of the undelivered elements includes the fair value of the installation plus the fair value of all other undelivered elements. The amount allocated to installation is based upon the fair value of the service performed, including labor, which is based upon the estimated time to complete the installation and hourly rates, and material components. The fair value of all other undelivered elements is based upon the price charged when these elements are sold separately. System revenue is generally recognized upon delivery provided title and risk of loss has passed to the customer, evidence of an arrangement exists, fees are contractually fixed or determinable, collectability is reasonably assured, and there are no uncertainties regarding customer acceptance. Revenue from installation services is generally recognized at the time the installation process is completed. The fair value of non-standard warranty is deferred at the time of shipment and recognized ratably over the duration of the non-standard warranty period. Revenue for other elements is recognized at the time products are shipped or the related services are performed.

ONI's management believes recognition of system revenue at the time of delivery is appropriate because the installation process has been established to be routine and commercially inconsequential. ONI believes the risk of failure to complete a system installation is remote. In addition, all other undelivered elements are not essential to the systems functionality.

In the limited instances where the terms of a customer agreement require customer acceptance, ONI will defer the recognition of system revenue until written customer acceptance of the system is obtained. This deferral period is generally within one to two months of shipment.

Revenue recognition from the sale of products to international distributors is subject to these same criteria. For all orders placed by distributors, ONI requires an approved sales order, and it ensures that all the terms of the sales order are proper and within the guidelines of the distribution agreement. International sales are generally subject to end customer acceptance and revenue recognition is deferred until acceptance is received. ONI does not offer any special right of return to its distributors or the end customers. ONI historically has not made concessions to its distributors with respect to terms and conditions of its sales orders.

Service revenue includes revenue from service maintenance contracts, time and material services, and spare parts sales. Revenue related to service maintenance contracts is recognized ratably over the duration of the contracts. Revenue related to time and material services is recognized when the services are performed. Revenue related to spare parts sales is recognized upon shipment of the spare part. Costs related to service revenues are recorded when delivery of the underlying service or part is incurred.





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*Allowance for Doubtful Accounts.* ONI maintains an allowance for doubtful accounts for the estimated losses resulting from the inability of its customers to make required payments. The amount recorded in the allowance is based primarily upon management's evaluation of the financial condition of ONI's customers. In determining these estimates, ONI examines its receivables and reviews customer accounts to identify any specific collection issues. If the financial condition of any of ONI's customers were to deteriorate so as to impair the ability to make payment, ONI could change the allowance by a material amount. ONI's failure to estimate accurately the losses for doubtful accounts and ensure that payments are received on a timely basis could have a material adverse effect on its results of operations and financial condition. The allowance for doubtful accounts was \$10,000 at March 31, 2005 and \$40,000 at December 31, 2004. ONI historically has not had to write off any accounts as bad debts.

*Inventories.* Inventories are carried at the lower of cost (first-in, first-out) or market. ONI records an allowance for estimated excess and obsolete inventory to adjust inventory to its net realizable value. The allowance is determined using management's assumptions of materials usage, based on estimates of demand and market conditions. If actual market conditions are or become less favorable than those projected by management, additional inventory write-downs may be required. At March 31, 2005 and December 31, 2004, ONI had a \$46,000 and \$114,000 reserve for excess and obsolete inventory, respectively.

*Warranty.* ONI warrants its systems to customers typically for a period of one year from the date of shipment. Estimated costs to provide warranty services are accrued at the time of revenue recognition. The fair value of revenue related to non-standard warranty is deferred until the related services are performed. Factors that affect ONI's warranty liability include the number of units sold, historical and anticipated rates of warranty claims, and costs per claim. ONI periodically assesses the adequacy of its recorded warranty liabilities and adjusts the amounts to reflect more current information. To the extent ONI experiences increased or decreased warranty claim activity or increased or decreased costs associated with servicing those claims, ONI's warranty accrual will increase or decrease, respectively, resulting in decreased or increased gross profit. If warranty claims exceed ONI's estimate of its warranty obligations, ONI could incur significant additional expenses, which could have a material adverse effect on its results of operations and financial condition.

*Deferred Revenue.* Deferred revenue primarily consists of amounts received from customers for which the earnings process has not been completed. Deferred revenue typically includes customer down payments, installation and training, non-standard warranty and undelivered product options.

*Stock Based Compensation.* Awards under ONI's stock option plan are accounted for in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, also known as APB 25. Under APB No. 25, the difference, if any, between the fair market value of shares of ONI's common stock, as determined by the ONI's board of directors on the date of the grant, and the exercise price of the option is recognized as compensation expense ratably over the vesting term. Options granted to non-employees are accounted for under variable accounting in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* and EITF 96-18, *Accounting for Equity Instruments That are Issued to Other than Employees*.

*Deferred Income Taxes.* At December 31, 2004, ONI had \$9,588,000 of deferred income tax assets relating primarily to net operating loss carryforwards and research and development tax credit carryforwards, for which a full valuation allowance has been established to reflect the uncertainty of sufficient future taxable income to utilize the available deferred tax amounts. ONI expects to record a full valuation allowance on future tax benefits until it can sustain an appropriate level of profitability. However, going forward should ONI's becoming profitable provide sufficient evidence, in accordance with the provisions of SFAS No. 109, to support the ultimate realization of income tax benefits attributable to net operating losses, tax credit carryforwards, and other deductible temporary differences, a reduction in the valuation allowance may be recorded and the carrying value of deferred tax assets may be increased, resulting in a non-cash credit to earnings. The use of any operating loss carryforwards may be limited due to provisions under Internal Revenue Code Section 382.

**New Accounting Pronouncements**

*FIN 46.* In January 2003, the FASB issued Financial Interpretation No. 46, *Consolidation of Variable Interest Entities - An Interpretation of ARB No. 51*, also known as FIN 46. FIN 46 is an interpretation of

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Accounting Research Bulletin 51, *Consolidated Financial Statements*, and addresses consolidation by business enterprises of variable interest entities, or VIEs. VIEs are entities over which control is achieved through means other than voting rights, and the primary objective of this interpretation is to provide guidance on the identification of, and financial reporting for, such entities. FIN 46 requires an enterprise to consolidate a VIE if that enterprise has a variable interest that will absorb a majority of the entity's expected losses if they occur, receive a majority of the entity's expected residual returns if they occur or both. An enterprise shall consider the rights and obligations conveyed by its variable interests in making this determination. In December 2003, the FASB issued FIN 46 (revised December 2003), *Consolidation of Variable Interest Entities*, also known as FIN 46-R, to address certain implementation issues. ONI will be required to adopt FIN 46-R in fiscal 2005, except variable interest entities created after December 31, 2003 for which adoption of the provisions of FIN 46-R will be required to be applied upon ONI's initial involvement with the activity. ONI does not believe the adoption of FIN 46 will have a material impact on its financial statements.

*SFAS No. 123(R)*. In December 2004, the FASB issued SFAS No. 123(R) (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and Amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is not an alternative. SFAS No. 123(R) must be adopted no later than January 1, 2006. ONI expects to adopt SFAS No. 123(R) on January 1, 2006.

SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods: a modified prospective approach or a modified retrospective approach. Under the modified prospective approach, compensation cost is recognized beginning with the effective date based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and the requirements of SFAS No. 123(R) for all awards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested on the effective date. The modified retrospective approach includes the requirements of the modified prospective approach but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all prior periods presented or prior interim periods of the year of adoption. ONI is evaluating which method to adopt.

As permitted by SFAS No. 123, ONI currently accounts for the share-based payments to employees using APB Opinion No. 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of the fair value method will have a significant impact on ONI's results of operations, although it will have no impact on its overall financial position. The impact of the adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had ONI adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in note 2 to ONI's financial statements.

SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than an operating cash flow under current accounting literature. Since ONI does not have the benefit of tax deductions in excess of recognized compensation cost, because of ONI's net operating loss position, the change will have no immediate impact on ONI's consolidated financial statements.

*SFAS No. 150*. In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, was issued. SFAS No. 150 establishes standards for classifying and measuring as liabilities certain financial instruments with characteristics of both liabilities and equity, including redeemable preferred stock. The provisions of SFAS No. 150 are effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. For private companies, mandatorily redeemable financial



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instruments, as defined, are subject to the provisions of this statement for the fiscal period beginning after December 15, 2004. ONI does not believe the adoption of SFAS No. 150 will have a material impact on its financial statements.

*SFAS No. 151.* In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an Amendment of ARB 43, Chapter 4*. SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS No. 151 requires that idle facility expense, excessive spoilage, double freight, and rehandling costs be recognized as current period charges. In addition, SFAS No. 151 requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. However, early adoption is permitted for inventory costs incurred during fiscal years beginning after November 2004. ONI plans to adopt SFAS No. 151 on January 1, 2006. ONI is assessing what effect, if any, adopting SFAS No. 151 will have on its financial position or results of operations.

## **Market Risk Exposures**

ONI's primary market risk exposure is in the area of foreign currency exchange rate risk. Under ONI's agreement with GE Medical Systems for the supply of the OrthOne magnet, ONI is obligated to remit payment to GE Medical Systems in British pounds sterling. ONI's obligations under this agreement for the year ended December 31, 2004 fluctuated by approximately 26% due to movement in the exchange rate. ONI was obligated to pay an additional approximately \$389,000 due to exchange rate fluctuations. In 2005, if the dollar weakens by 10% ONI would be obligated to pay approximately \$404,000 in foreign exchange rate losses.

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**UNAUDITED PRO FORMA COMBINED CONSOLIDATED FINANCIAL DATA OF ONI AND NOVOSTE**

The following unaudited pro forma combined consolidated financial statements combine our historical consolidated balance sheet and statements of operations with those of ONI, giving effect to the merger using the purchase method of accounting. The unaudited pro forma combined statements of continuing operations for the year ended December 31, 2004, and the three months ended March 31, 2005, are presented as if the merger had been completed on January 1, 2004. The unaudited pro forma combined balance sheet is presented as if the merger had occurred on March 31, 2005.

U.S. generally accepted accounting principles require that one of the two companies in the transaction be designated as the acquirer for accounting purposes. ONI has been designated as the accounting acquirer because immediately after the merger its stockholders are expected to hold more than 50% of our common stock, a majority of our board of directors will be ONI designees and all members of management will be former ONI officers. Our historical statements of operations have been adjusted for the pro forma impact of the disposition or wind-down of the VBT business that is expected to occur about the same time as the merger. These adjustments are labeled as "VBT Adjustment" in the unaudited pro forma combined financial statements.

The merger of Novoste and ONI will be accounted for as a reverse acquisition under the purchase method of accounting because of the factors discussed above. Under this accounting treatment, ONI will be considered the acquiring entity and Novoste will be considered the acquired entity. The financial statements of the combined company after the merger will reflect the financial results of ONI on a historical basis after giving effect to the exchange ratio to historical share-related data, and will include the results of operations of Novoste from the effective date of the merger.

Under the purchase method of accounting, the aggregate consideration paid is allocated to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values on the transaction date. We preliminarily estimate that the fair value of the net assets acquired will approximate the estimated purchase price, however, the actual amounts recorded as of the completion of the merger may differ materially from the information presented in these unaudited pro forma combined consolidated financial statements.

The pro forma adjustments to the March 31, 2005 financial statements reflect the changes in the estimated assets and liabilities and the shareholder's equity that would have occurred had the merger with ONI occurred on that date. The pro forma adjustments also reflect elimination entries arising from combining the financial statements of ONI and Novoste, with ONI being designated as the accounting acquirer.

These unaudited pro forma combined consolidated financial statements should be read in conjunction with our historical consolidated financial statements and accompanying notes included elsewhere in this proxy statement and the historical financial statements and accompanying notes of ONI included elsewhere in this proxy statement. The unaudited pro forma combined consolidated financial statements are not necessarily indicative of the consolidated results of operations or financial condition of the combined company that would have been reported had the merger been completed as of the dates presented, and are not necessarily representative of the future consolidated results of operations or financial condition of the combined company.

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## UNAUDITED PRO FORMA COMBINED CONSOLIDATED BALANCE SHEET

AS OF MARCH 31, 2005

(IN THOUSANDS)

	Historical Novoste	Historical ONI	Pro Forma Adjustments	note	Adjusted Combined Historical	VBT Adjustments	note	Pro Forma Combined
Cash and cash equivalents	\$ 20,484	\$ 450		(1)	\$ 20,934			\$ 20,934
Short-term investments	4,103				4,103			4,103
Restricted cash	75	50			125			125
Accounts receivable, net	894	1,223			2,117	(894)	(9)	1,223
Inventory, net of reserves	203	2,553			2,756	(203)	(9)	2,553
Rights under reseller agreements		416			416			416
Assets held for sale	462				462	(462)	(9)	0
Prepaid and other current assets	634	555			1,189			1,189
<b>Total current assets</b>	<b>26,855</b>	<b>5,247</b>			<b>32,102</b>	<b>(1,559)</b>		<b>30,543</b>
Property and equipment, net	188	489			677	(188)	(9)	489
Rights under reseller agreements		523			523			523
Other assets		805	(220)	(1,3)	585			585
<b>Total assets</b>	<b>\$ 27,043</b>	<b>\$ 7,064</b>	<b>\$ (220)</b>		<b>\$ 33,887</b>	<b>\$ (1,747)</b>		<b>\$ 32,140</b>
Accounts payable	\$ 1,137	\$ 2,515	\$		\$ 3,652	\$		\$ 3,652
Accrued expenses	4,755	1,896	5,933	(2,3,4,5)	12,584	(2,423)	(9)	10,161
Deferred revenue	1,345	1,354			2,699			2,699
Other liabilities		1,277			1,277			1,277
<b>Total current liabilities</b>	<b>7,237</b>	<b>7,042</b>	<b>5,933</b>		<b>20,212</b>	<b>(2,423)</b>		<b>17,789</b>
Long-term liabilities		660			660			660
<b>Total liabilities</b>	<b>7,237</b>	<b>7,702</b>	<b>5,933</b>		<b>20,872</b>	<b>(2,423)</b>		<b>18,449</b>
Redeemable convertible preferred stock		11,800	(11,800)	(7)				
Shareholders equity (deficit):								
Common stock	164	59	137	(6,7)	360			360
Additional paid-in capital	187,848	12,900	(156,811)	(3,6,7,8)	43,937			43,937
Other comprehensive income	744		(744)		0			0
Retained earnings (deficit)	(168,777)	(25,397)	162,892	(2,3,4,5,6,7)	(31,282)	676	(9)	(30,606)
Treasury stock	(172)		172	(8)	0			0
Unearned compensation	(1)		1	(8)	0			0
<b>Total equity (deficit)</b>	<b>19,806</b>	<b>(12,438)</b>	<b>5,647</b>		<b>13,015</b>	<b>676</b>		<b>13,691</b>
<b>Total liabilities, preferred stock &amp; equity</b>	<b>\$ 27,043</b>	<b>\$ 7,064</b>	<b>\$ (220)</b>		<b>\$ 33,887</b>	<b>\$ (1,747)</b>		<b>\$ 32,140</b>

See accompanying notes to Unaudited Pro Forma Combined Consolidated Financial Statements



**Table of Contents****UNAUDITED PRO FORMA COMBINED CONSOLIDATED STATEMENT OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2005****(IN THOUSANDS, EXCEPT PER SHARE DATA)**

	<b>Historical Novoste</b>	<b>Historical ONI</b>	<b>Pro Forma Adjustments</b>	<b>note</b>	<b>Adjusted Combined Historical</b>	<b>VBT Adjustments</b>	<b>note</b>	<b>Pro Forma Combined</b>
Total revenue	\$ 3,413	\$ 2,629	\$		\$ 6,042	\$ (3,413)	(1)	\$ 2,629
Total cost of revenue	4,118	2,125			6,243	(4,118)	(1)	2,125
Gross profit (loss)	(705)	504			(201)	705		504
Research and development	434	602			1,036	(434)	(1)	602
Sales and marketing	2,702	977			3,679	(2,702)	(1)	977
General and administrative	2,878	515			3,393	(2,478)	(1)	915
Total operating expenses	6,014	2,094			8,108	(5,614)		2,494
Loss from operations	(6,719)	(1,590)			(8,309)	6,319		(1,990)
Interest income	140	5			145			145
Interest expense		(9)			(9)			(9)
Other income (expense)	25	4	(25)	(3)	4			4
Total other income	165	0	(25)		140			140
Net loss	\$ (6,554)	\$ (1,590)	\$ (25)		\$ (8,169)	\$ 6,319		\$ (1,850)
Number of shares								39,255
Net loss per share (basic & diluted)								\$ (0.05)

See accompanying notes to Unaudited Pro Forma Combined Consolidated Financial Statements

**Table of Contents****UNAUDITED PRO FORMA COMBINED CONSOLIDATED STATEMENT OF****OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2004****(IN THOUSANDS, EXCEPT PER SHARE DATA)**

	<b>Historical Novoste</b>	<b>Historical ONI</b>	<b>Pro Forma Adjustments</b>	<b>note</b>	<b>Adjusted Combined Historical</b>	<b>VBT Adjustments</b>	<b>note</b>	<b>Pro Forma Combined</b>
Total revenue	\$ 23,268	\$ 8,887	\$		\$ 32,155	\$ (23,268)	(1)	\$ 8,887
Total cost of revenue	16,111	7,826			23,937	(16,111)	(1)	7,826
Impairment charges	7,630				7,630	(7,630)	(1)	0
Gross profit (loss)	(473)	1,061			588	473		1,061
Research and development	4,633	1,843			6,476	(4,633)	(1)	1,843
Sales and marketing	12,558	3,392			15,950	(12,558)	(1)	3,392
General and administrative	8,036	1,822			9,858	(6,436)	(1)	3,422
Impairment charges	1,719				1,719	(1,719)	(1)	0
Total operating expenses	26,946	7,057			34,003	(25,346)		8,657
Loss from operations	(27,419)	(5,996)			(33,415)	25,819		(7,596)
Interest income	386	19			405			405
Interest expense	(3)	(14)	3	(2)	(14)			(14)
Other income (expense)	115	(9)	(115)	(3)	(9)			(9)
Total other income (expense)	498	(4)	(112)		382			382
Net loss	\$ (26,921)	\$ (6,000)	\$ (112)		\$ (33,033)	\$ 25,819		\$ (7,214)
Number of shares								39,255
Net loss per share (basic & diluted)								\$ (0.18)

See accompanying notes to Unaudited Pro Forma Combined Consolidated Financial Statements

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**NOTES TO UNAUDITED PRO FORMA  
COMBINED CONSOLIDATED FINANCIAL STATEMENTS**

**Notes to Pro Forma Combined Consolidated Balance Sheet as of March 31, 2005**

This balance sheet presents the combined balance sheets of Novoste and ONI as though the transaction had occurred on March 31, 2005, adjusted for activity related to the transaction as described below:

*Note 1 Record loan from Novoste to ONI.* At the time of the signing of the merger agreement, Novoste provided an unsecured loan of \$3,000,000 to ONI. Because this is a loan between merged entities, there is no overall effect on the combined statement.

*Note 2 Record change of control payments.* Contracts with certain officers of Novoste contain provisions for payment should control of the company change. Under the terms of the merger agreement, control is expected to change from current Novoste management to ONI management. The amount of \$2,373,000 will be disbursed immediately following completion of the merger.

*Note 3 Record liability for transaction costs.* Upon completion of the merger, Novoste will become obligated to its financial advisor for transaction fees of approximately \$800,000 (a portion of which became payable at the time the merger agreement was signed). Upon completion of the merger, ONI will become obligated to its financial advisor for transaction fees of approximately \$500,000. In addition, an estimated \$770,000 for legal and other professional fees for Novoste and ONI is included for incurred or expected to be incurred expenses.

*Note 4 Record liability for insurance obligations.* Under the terms of the merger agreement, Novoste will provide tail liability insurance and D&O insurance covering any claims arising from pre-merger activity. Premiums are estimated to be \$800,000.

*Note 5 Record severance obligations for Novoste employees.* Prior to the signing of the merger agreement, Novoste provided employee incentives to remain with the company to manage the wind-down of the VBT business and attend to the business of running the company prior to completion of the merger. These incentives include retention bonuses, payment of health insurance and outplacement assistance when employment ends. These incentives along with the severance obligations total approximately \$910,000 and are expected to be paid out completely by the end of 2005.

*Note 6 Implied stock dividend to holders of ONI Series A preferred stock.* Under an agreement between ONI and the holders of ONI's Series A preferred stock, the holders of Series A preferred stock are to receive a premium as compared to what such holders would have otherwise received in the merger if they had converted their shares to ONI common stock immediately prior to the merger. This premium will be recorded as a stock dividend for accounting purposes. This pro forma presentation assumes that a dividend of 4,562,000 shares of Novoste common stock will be issued to the holders of ONI Series A preferred stock. The aggregate value for the stock dividend is \$5,885,000, or 50% of the value of the preferred stock prior to the transaction.

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*Note 7 Exchange ONI Series A preferred stock.* The remaining value of \$11,800,000 of ONI Series A preferred stock will be exchanged for 9,147,000 shares of Novoste common stock valued at \$11,709,000.

*Note 8 Adjust the equity accounts of Novoste and exchange ONI shares.* Under the accounting treatment, which considers Novoste to be the entity acquired, our historical equity is eliminated and the aggregate purchase price, which is estimated to be \$14,623,000 as of March 31, 2005, is allocated to the fair value of the net assets acquired. We preliminarily estimate that the fair value of the net assets acquired approximates the estimated purchase price. Novoste's management expects this value to decline to \$12,500,000 between the date of the pro forma balance sheet and the completion of the merger sometime in the third quarter of 2005. In addition, ONI

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common shares will be exchanged for Novoste common shares. Based on 16,334,780 shares of our common stock outstanding, and assuming that the value of our net cash assets at closing provides for a Novoste valuation of \$12,500,000, we currently expect to issue an aggregate of 22,720,304 shares of our common stock and to assume options and warrants to purchase an aggregate of 3,640,944 shares of our common stock if the merger is completed. At the conclusion of the transaction we expect to have 39,255,084 shares of common stock outstanding including approximately 200,000 shares of restricted common stock we and ONI anticipate will be granted to non-employee members of the board of directors of the combined company as consideration for their service on the board.

*Note 9 Remove items related to the VBT business being sold.* We expect to either substantially complete the wind-down of the VBT business as of the merger date, or we may be able to find a buyer of the VBT business by the merger date. The fact that the VBT business will cease or be sold makes it appropriate to exclude balance sheet items that are related to the VBT business. Any purchaser may acquire the net assets of the business, including among other things the customer list, accounts receivable, production equipment and radiation devices, accounts payable, AEA minimum purchase obligations, decommissioning responsibilities of the radiation production facility in Germany, and miscellaneous other liabilities associated with the VBT business. In lieu of a sale, certain liabilities may remain on the balance sheet.

**Notes to Pro Forma Combined Consolidated Statements of Operations for three months ended March 31, 2005 and year ended December 31, 2004**

These statements of operations include the combined income statements of Novoste and ONI as though the transaction had occurred on January 1, 2004, adjusted for activity related to the transaction as described below:

*Note 1 Eliminate activity related to the vascular brachytherapy (VBT) business.* Prior to the merger agreement, Novoste concluded that the VBT business was not viable as a stand-alone business and began winding down the activity. If the merger had been completed prior to January 1, 2004, the year and first quarter of 2005 would not have had any VBT business except incidental activity related to the wind-down, which is not indicative of operations going forward for the combined entities. We expect to either substantially complete the wind-down of the VBT business as of the merger date, or we may be able to find a buyer for the VBT business by the merger date. Going forward, ONI will continue to incur costs related to the record keeping and filing of documents, payments to directors on the board, higher directors and officers insurance, higher professional services for legal and accounting services, and other costs related to operating as a company with publicly held stock. These costs of approximately \$400,000 per quarter, or \$1,600,000 per year, have not been eliminated from Novoste's historical financial statements.

*Note 2 Eliminate interest expense.* Under the terms of the merger, cash availability will reduce the need for borrowing. ONI interest relates in part to its line of credit, which will remain in place post merger.

*Note 3 Eliminate other income.* These amounts relate to the sale of assets during the wind-down of the VBT business. These are non-recurring and not indicative of operations going forward for the combined entities.

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**APPROVAL OF THE NOVOSTE SHARE INCREASE AMENDMENT**

**(Proposal 2)**

Our board of directors has approved, subject to shareholder approval, an amendment to our articles of incorporation to increase the number of authorized shares of our common stock from 25,000,000 to 75,000,000. A copy of the proposed certificate of amendment is attached as *Annex C* to this proxy statement. You are urged to read the certificate of amendment carefully as it is the legal document that governs this amendment to the articles of incorporation. Although we are asking for shareholder approval of this proposal, if for any reason the merger is not completed, this proposal will not be implemented.

**Description of Amendment**

Under our articles of incorporation, we are currently authorized to issue up to 25,000,000 shares of common stock and 5,000,000 shares of preferred stock.

As of the record date, there were 16,334,780 shares of our common stock issued and outstanding. In addition, 1,915,591 shares of common stock are reserved for issuance upon the exercise of outstanding options. Of these currently outstanding options, 141,000 are expected to remain outstanding after completion of the merger because they are held by directors expected to remain on our board after completion of the merger. The remaining options are expected to be cancelled at closing, or expire pursuant to their terms in the months following the merger. No shares of preferred stock are currently issued and outstanding.

Under the terms of the merger agreement, if the merger is completed, we will issue shares of our common stock to the holders of ONI's capital stock. In addition, all outstanding and unexercised options and warrants to purchase shares of ONI equity securities will be assumed by us and be converted and become options and warrants to acquire shares of our common stock. The total number of shares of our common stock to be issued pursuant to the merger agreement (including upon exercise of assumed ONI options and warrants) will be determined at the time of the closing of the merger based on a formula that values us at the value of our net cash assets at closing and values ONI at \$20,000,000 (solely for purposes of this calculation).

However, under the merger agreement, if the amount of our net cash assets at closing is less than \$10,000,000, ONI must either accept a Novoste valuation of \$10,000,000 or terminate the agreement. As a result, the Novoste valuation cannot be less than \$10,000,000, even if the amount of our net cash assets at closing is less than \$10,000,000. See *Approval of Issuance of Shares in the ONI Merger Terms of the Merger Agreement* *Merger Consideration* for a further description.

Assuming that the outstanding number of shares of our common and preferred stock (including options to acquire common stock held by continuing Novoste directors) remains at the numbers stated above, the maximum number of shares of our common stock that could potentially be issuable to the holders of ONI's equity securities (including shares issuable pursuant to the assumption of outstanding ONI options and warrants) is 32,951,560 shares, which would occur if the amount of our net cash assets at closing is \$10,000,000 or less, resulting in a Novoste valuation of \$10,000,000.

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The proposed amendment to our articles of incorporation will authorize the issuance of up to an additional 50,000,000 shares of our common stock. This increase will provide a sufficient number of authorized shares of common stock for issuances pursuant to the merger agreement and for reasonably foreseeable future issuances by the combined company pursuant to benefit plans or otherwise.

### **Vote Required**

The approval of the amendment to our articles of incorporation to increase the authorized number of shares of our common stock requires that the number of votes cast by the shareholders at the special meeting in favor of the proposal exceed the number of votes cast against the proposal. Only shares that are voted FOR or AGAINST the proposal will be counted towards the vote requirement. Thus, shares represented at the meeting that are marked ABSTAIN, and broker non-votes, if any, will not be counted towards the vote requirement. Additionally, if you do not complete and return a proxy card and do not vote in person, there will be no effect on the outcome of the vote.

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**Reasons for the Amendment; Effect of the Amendment**

The amendment to our articles of incorporation described in this proposal is required to complete the merger. In the opinion of our board of directors, the amendment is advisable and in the best interests of our shareholders. If the amendment is not approved, we will not be able to complete the merger and the other transactions contemplated by the merger agreement.

**Recommendation of our Board of Directors**

On May 16, 2005, our board of directors concluded unanimously (with one director recused from the matters) that the merger agreement and the share issuance are in the best interests of our shareholders, authorized and approved the merger agreement, the merger and the share issuance, and recommended that our shareholders approve this proposal, as well as the share issuance and the amendment to our articles of incorporation to change our name. See "Approval of Issuance of Shares in the ONI Merger" Recommendation of our Board of Directors and Reasons for the Merger for a further description.

**OUR BOARD OF DIRECTORS RECOMMENDS A VOTE FOR PROPOSAL 2.**



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**APPROVAL OF THE NOVOSTE NAME CHANGE AMENDMENT**

**(Proposal 3)**

Our board of directors has approved, subject to shareholder approval, an amendment to our articles of incorporation to change our name from Novoste Corporation to ONI Medical Systems, Inc. A copy of the proposed certificate of amendment is attached as *Annex D* to this proxy statement. You are urged to read the certificate of amendment carefully as it is the legal document that governs this amendment to the articles of incorporation. Although we are asking for shareholder approval of this proposal, if for any reason the merger is not completed, this proposal will not be implemented.

**Description of Amendment**

Under the terms of the merger agreement, in order to complete the merger, we must change our name from Novoste Corporation to ONI Medical Systems, Inc. upon the completion of the merger.

**Vote Required**

The approval of the amendment to our articles of incorporation to change our name to ONI Medical Systems, Inc. requires that the number of votes cast by the shareholders at the special meeting in favor of the proposal exceed the number of votes cast against the proposal. Only shares that are voted FOR or AGAINST the proposal will be counted towards the vote requirement. Thus, shares represented at the meeting that are marked ABSTAIN, and broker non-votes, if any, will not be counted towards the vote requirement. Additionally, if you do not complete and return a proxy card and do not vote in person, there will be no effect on the outcome of the vote.

**Reasons for the Amendment; Effect of the Amendment**

Approval of the amendment to our articles of incorporation described in this proposal is a condition of our and ONI's respective obligations to complete the merger. In the opinion of our board of directors, the amendment is advisable and in the best interests of our shareholders. If the amendment is not approved, we will not be able to complete the merger and the other transactions contemplated by the merger agreement unless both we and ONI agree to waive this condition to closing.

**Recommendation of our Board of Directors**

On May 16, 2005, our board of directors concluded unanimously (with one director recused from the matters) that the merger agreement and the share issuance are in the best interests of our shareholders, authorized and approved the merger agreement, the merger and the share issuance, and recommended that our shareholders approve this proposal, as well as the share issuance and the amendment to our articles of incorporation to increase the authorized number of shares of our common stock. See *Approval of Issuance of Shares in the ONI Merger Recommendation of our Board of Directors and Reasons for the Merger* for a further description.

**OUR BOARD OF DIRECTORS RECOMMENDS A VOTE FOR PROPOSAL 3.**

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**ELECTION OF DIRECTORS**

**(Proposal 4)**

Under our articles of incorporation, our board of directors is divided into three classes of directors (Classes I, II and III), each of which has a three-year term. The Class III directors have terms that expire at the special meeting of shareholders in lieu of an annual meeting, the Class I directors have terms that expire at the 2006 annual meeting, and the Class II directors have terms that expire at the 2007 annual meeting.

The articles of incorporation also provide that the number of directors will be fixed from time to time exclusively by the board of directors, but shall consist of not more than twelve nor less than six directors, with no class of directors consisting of more than four nor less than two directors. The board of directors currently has seven members. Class I currently consists of three directors and each of Class II and Class III currently consists of two directors.

At the special meeting, two directors will be elected to serve as Class III directors whose terms expire in 2008. The board of directors has nominated Thomas D. Weldon and Charles E. Larsen to be elected as Class III directors, each for a three-year term.

If any nominee should become unavailable for election for any presently unforeseen reason, it is intended that the proxies will be voted for such substitute nominee as may be designated by the present board of directors.

**Vote Required**

A plurality of the total votes cast by the holders of our common stock is required to elect each of the two directors. You may vote either **FOR** each director nominee or you may **WITHHOLD AUTHORITY** for each director nominee separately. Only shares that are voted in favor of a particular nominee will be counted towards that nominee's achievement of a plurality. Thus, shares represented at the meeting that are not voted for a particular nominee, shares present in person or represented by proxy where the shareholder properly withholds authority to vote for the nominee, and broker non-votes, if any, will not be counted towards the nominee's achievement of a plurality.

**Changes to our Board if the Merger is Approved and Consummated**

If proposals 1, 2 and 3 are approved and we complete the merger with ONI, Mr. Weldon, J. Stephen Holmes and William E. Whitmer will resign effective immediately upon the closing, our board will fix the number of directors at nine, and 4 new directors designated by ONI and one designated by us will be appointed, as further described in **Approval of Issuance of Shares in the ONI Merger Terms of the Merger Agreement Board of Directors of the Combined Company**.

**OUR BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS**

**A VOTE FOR EACH OF THE NOMINEES LISTED ABOVE.**

**Information as to Nominees and Continuing Directors**

*Class III Directors Nominated for Election at the Special Meeting for Terms Expiring in 2008*

**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

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1992, prior to its sale. His 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 Continuing 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 to joining Teleflex, 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 an independent consultant for venture capital firms, including 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. Mr. Shapiro is also currently a director of ONI. See Information about ONI Executive Officers and Directors of ONI.

**William E. Whitmer**, age 72. 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. in 2002. Mr. Whitmer is a Certified Public Accountant and management consultant. From 1989 until 1992, he was a partner of Ernst & Young LLP, having served as the Associate Managing Director of that firm's 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 Continuing Directors Whose Terms Expire in 2007***

**Alfred J. Novak**, age 57. Mr. Novak was elected by our board of directors to the position of a director and President and Chief Executive Officer of Novoste on October 16, 2002. Since December 1997, he has served as Chairman of the Board of Directors of ProRhythm, Inc., a start-up medical device company engaged in electrophysiology. In September 1998, he co-founded and was a management board member of Syntheon, LLC, a company that developed minimally invasive medical devices for the vascular and endoscopic markets. Mr. Novak also served

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as Chairman of the Board of Directors of Orbus Medical Technologies, Inc., an interventional vascular company, from April 1998 until March 2005, when Orbus was acquired. From July 1996 until January 1998, Mr. Novak was President, Chief Executive Officer and a director of Biosense, Inc., a company that

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developed a position sensor incorporated into catheters and used in interventional cardiology, electrophysiology, and image guided surgery, and which was acquired by Johnson & Johnson in October 1997. Mr. Novak was employed by Cordis Corporation in April 1984 and served as its Vice President and Chief Financial Officer and a member of the executive committee until Cordis was acquired by Johnson & Johnson in February 1996. Mr. Novak received his M.B.A. from the Wharton School of the University of Pennsylvania and earned his B.S. at the U.S. Merchant Marine Academy.

**Judy Lindstrom**, age 59. Ms. Lindstrom was elected a director of Novoste in June 2002, by our 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 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.

## **Governance of Novoste**

Our board of directors has a standing audit committee, stock option and compensation committee and nominating and corporate governance committee. Our board of directors is composed of a majority of independent directors, and all of the committees are composed entirely of independent directors, as the term is defined in the listing standards of the Nasdaq Stock Market. In addition, the audit committee is composed entirely of independent directors as the term is defined in Section 10A(m)(3) of the Securities Exchange Act of 1934. Our board of directors has adopted a charter for each of the three standing committees and corporate governance principles that address the make-up and functioning of the board. Our board of directors has also adopted a code of business conduct and ethics that applies to all of our employees, officers and directors. Copies of the audit committee charter, the nominating and corporate governance committee charter and code of business conduct and ethics were attached to our 2004 proxy statement as Appendices A, B and C, respectively.

## ***Meetings of the Board of Directors and its Committees***

During 2004, there were 12 meetings of our board of directors, one of which was a telephonic meeting. In addition, the board of directors acted on one occasion by unanimous written consent in lieu of a meeting. No director attended fewer than 75% of the aggregate number of meetings of the board of directors held during the period in 2004 in which he or she was a director and meetings held by committees of the board of directors during the period in 2004 in which he or she served as a member of the committee.

## ***Audit Committee***

The audit committee is currently comprised of Ms. Lindstrom and Messrs. Whitmer and Holmes, with Mr. Whitmer serving as chairman. 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 that all of the members of the audit committee are independent for purposes of current listing standards of the Nasdaq Stock Market and Section 10A(m)(3) of the Securities Exchange Act of 1934.

The audit committee:

is directly responsible for the appointment, compensation and oversight of the work of the registered public accounting firm employed by us for the purpose of preparing and issuing an audit report on our financial statements;



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assists the board of directors in fulfilling its responsibilities by overseeing

processes involved in the preparation and review of the financial reports provided to the public and the audits of our financial statements,

our system of internal controls regarding finance, financial reporting, and accounting, and the legal compliance and ethics procedures that management and the board of directors have established, and

our auditing, accounting and financial reporting processes generally; and

performs the other functions required of audit committees of public companies under applicable laws, rules and regulations and the requirements of The Nasdaq Stock Market.

A full description of the duties and responsibilities of the audit committee is stated in its charter, which was attached to our 2004 proxy statement as Appendix A. The audit committee met seven times during 2004.

### *Stock Option and Compensation Committee*

The stock option and compensation committee of the board of directors is currently comprised of Ms. Lindstrom and Messrs. Shapiro and Holmes, with Mr. Shapiro serving as chairman. This committee establishes compensation policies and approves compensation for our executive officers and administers our stock option plans. This committee met 12 times during 2004, which included six telephonic meetings. In addition, the committee acted on one occasion by unanimous written consent in lieu of a meeting.

### *Nominating and Corporate Governance Committee*

The nominating and corporate governance committee of the board of directors is currently comprised of Ms. Lindstrom and Messrs. Holmes, Shapiro and Whitmer, with Ms. Lindstrom serving as chairperson. This committee is responsible for recommending to the board of directors potential candidates to be nominated for election or appointment as our directors as well as consideration of issues relating to our corporate governance. The nominating and corporate governance committee also considers shareholder suggestions regarding possible candidates for director as described below under Nomination of Directors. A full description of the duties and responsibilities of the nominating and corporate governance committee is stated in its charter, which was attached to our 2004 proxy statement as Appendix B. This committee was established in December 2003 and held two meetings in 2004.

### *Attendance by Directors at the Annual Meeting of Shareholders*

The board of directors has scheduled a board meeting in conjunction with our annual meeting of shareholders. Our directors are expected to attend the special meeting of shareholders in lieu of an annual meeting on September 14, 2005. All directors then serving on the board of directors attended the annual meeting held on June 15, 2004.

*Shareholder Communications with the Directors*

Novoste shareholders who want to communicate with the board of directors or any individual director can write to: Novoste Corporation, 3890 Steve Reynolds Boulevard, Norcross, Georgia 30093, Attention: Corporate Secretary. Your letter should state that you are a Novoste shareholder. All communications will be received and processed by our Corporate Secretary, who will present such communications to the board of directors.

The Corporate Secretary will:

forward the communication to the director or directors to whom it is addressed; or

forward the inquiry to our management for resolution (for example, where it is a request for information about Novoste or it is a stock-related matter).

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At each board meeting, the Corporate Secretary presents a summary of all shareholder communications received since the last meeting and makes the communications available to the directors on request.

### *Nomination of Directors*

As provided in its charter and our corporate governance principles, the nominating and corporate governance committee is responsible for identifying individuals qualified to become directors. The nominating and corporate governance committee seeks to identify director candidates based on input provided by a number of sources, including committee members, our other directors, our shareholders, our Chief Executive Officer or Chairman, and third parties such as professional search firms. In evaluating potential candidates for director, the nominating and corporate governance committee considers the entirety of each candidate's credentials.

Qualifications for consideration as a director nominee may vary according to the particular areas of expertise being sought as a complement to the existing composition of the board of directors. However, at a minimum, candidates for director must possess:

high personal and professional ethics and integrity;

ability to exercise sound judgment;

ability to make independent analytical inquiries;

willingness and ability to devote adequate time and resources to diligently perform board duties; and

appropriate and relevant business experience and acumen.

In addition to these minimum qualifications, the nominating and corporate governance committee also takes into account when considering whether to nominate a potential director candidate the following factors:

whether the person possesses specific industry expertise and familiarity with general issues affecting our business;

whether the person's nomination and election would enable the board to have a member that qualifies as an audit committee financial expert as that term is defined by the SEC in Item 401 of Regulation S-K;

whether the person would qualify as an independent director under the listing standards of the Nasdaq Stock Market;

the importance of continuity of the existing composition of the board of directors; and

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the importance of a diversified board membership, in terms of both the individuals involved and their various experiences and areas of expertise.

The nominating and corporate governance committee will consider director candidates recommended by shareholders provided such recommendations are submitted in accordance with the procedures set forth below. In order to provide for an orderly and informed review and selection process for director candidates, the board of directors has determined that shareholders who wish to recommend director candidates for consideration by the nominating and corporate governance committee must comply with the advance notice provisions and other requirements of Section 3.07 of our by-laws, as if such recommendation were a nomination. This notification must be received by us not later than June 16, 2006 and not earlier than May 17, 2006, and must provide information about the nominee's qualifications for board membership and other information required by the by-laws. Shareholders who intend to recommend a director candidate to the nominating and corporate governance committee for consideration are urged to obtain and thoroughly review a copy of our by-laws. To obtain a copy of our by-laws, shareholders should contact our Corporate Secretary at 4350 International Boulevard, Norcross, Georgia 30093. For additional information regarding our advance notice procedures, please review the information under the caption Other Business.

All candidates submitted by shareholders will be evaluated by the nominating and corporate governance committee according to the criteria discussed above and in the same manner as all other director candidates.

**Table of Contents****Executive Compensation and Other Information**

The following table provides a summary of the compensation paid or accrued by us during fiscal years 2004, 2003 and 2002 to our named executive officers, or our Chief Executive Officer and 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:

**Summary Compensation Table**

Name And Principal Position	Year	Annual Compensation			Long-Term	All Other Compensation (5)
		Salary	Bonus (2)	Other Annual Compensation (3)	Compensation (1)	
					Common	
					Stock Underlying	
					Options (4)	
<b>Alfred J. Novak</b>						
President and CEO (6)	2004	\$ 429,441	\$ 489,538	\$ 29,487 (7)	200,000	\$ 5,333
	2003	350,000	123,452	72,156 (7)	8,700	4,671
	2002	64,615	6,417		700,000	
<b>Robert N. Wood, Jr.</b>						
VP Marketing & Sales	2004	271,296	222,370		75,000	4,750
	2003	223,649	56,612		8,700	4,280
	2002	206,730	17,655		26,250	41,196
<b>Daniel G. Hall</b>						
VP and Corporate Secretary & General Counsel	2004	197,772	170,675		0	3,955
	2003	186,810	47,287		8,700	2,612
	2002	170,312	14,747		23,125	24,416
<b>Adam G. Lowe</b>						
VP Quality Assurance	2004	180,761	154,634		0	3,268
	2003	167,228	42,330		8,700	3,015
	2002	153,321	13,201		19,375	24,873
<b>Andrew M. Green</b>						
VP Scientific Affairs	2004	171,644	145,975			3,432
	2003	141,385	32,918		75,000	2,807
	2002	112,019	10,313		19,700	2,240

(1) 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.

(2) Bonus compensation for 2004 includes payments of executive retention bonuses, as described below under the caption Executive Retention Bonus Agreements below.

- (3) Except as provided in note 7 below, we did not pay any other annual compensation to the named executive officers during the fiscal years 2004, 2003 and 2002.
- (4) See Stock Options below for the exercise price and vesting terms of the options granted in 2004.
- (5) 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.
- (6) Mr. Novak joined Novoste as President and Chief Executive Officer on October 16, 2002.
- (7) 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.

**Table of Contents****Stock Options**

The following table provides certain information concerning options granted in fiscal year 2004 to our named executive officers.

**Option Grants in Fiscal Year 2004**

Name	Number of Securities		Exercise Price Per Share (2)	Expiration Date	Potential Realizable Value at	
	Underlying Options Granted (1)	% of Total Options Granted to Employees in Fiscal Year 2004			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	\$ 364,759	\$ 924,371
Robert N. Wood, Jr	75,000	8.5	2.90	7/15/2014	\$ 136,785	\$ 346,639
Daniel G. Hall	75,000	8.5	2.90	7/15/2014	\$ 136,785	\$ 346,639
Adam G. Lowe	75,000	8.5	2.90	7/15/2014	\$ 136,785	\$ 346,639
Andrew M. Green	75,000	8.5	2.90	7/15/2014	\$ 136,785	\$ 346,639

- (1) 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 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 before 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.

**Option Exercises and Holdings**

The following table provides certain information concerning the number and value realized on 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. On May 18, 2005, we entered into amendments to the termination agreements with each of these executive officers.



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As amended, each agreement provides that the executive officer a party to it will receive severance payments upon a change in control of Novoste, including completion of the merger with ONI. For a further description of these agreements and payments that will be due to our executive officers if the merger with ONI is completed, please see *Approval of Issuance of Shares in the ONI Merger* *Interests of Certain Novoste and ONI Persons in the Merger* *Change in Control Payments*.

### ***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 us during our 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 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 and \$166,675 for remaining in our employ through December 31, 2004 and March 31, 2005, respectively.

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 us 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 and \$62,275 for remaining in our employ through December 31, 2004 and March 31, 2005, respectively.

Mr. Lowe received \$111,500 and \$55,730 for remaining in our employ through December 31, 2004 and March 31, 2005, respectively.

Mr. Green received \$104,500 and \$52,250 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 us 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 that term is defined in his employment agreement), he will receive benefits as stated 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 that 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 the 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 us in March 2005. As a result, they each received a pro rated bonus payment, as further described above, for their retention as our 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.



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### ***Executive Employment Agreement***

On October 8, 2002, we entered into an employment agreement with Mr. Novak which stated 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 year (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 stated 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 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.

### ***Report of Stock Option and Compensation Committee***

The stock option and compensation committee of our board of directors is composed of three non-employee directors and is responsible for the administration of our compensation programs. During 2004, there was a change in the composition of the committee necessitated by the

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retirement from the board of directors of Dr. Donald Harrison, who was a non-employee member of the committee. Dr. Harrison was replaced on the committee by Stephen Holmes, also a non-employee director.

Our compensation programs have historically included base salary for executive officers and both annual and long-term incentive compensation programs. The programs have been designed to provide a competitive

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level of total compensation and include incentive and equity ownership opportunities linked to our performance and shareholder return.

### *Compensation Philosophy*

Our primary goal has been to align compensation with our business objectives and performance. The change in business strategies which occurred during 2004 required alteration of compensation philosophies so that we could maximize the retention of management in a period of uncertainty. In order to establish the relationship between executive compensation and the protection of shareholder value during this period, the committee adopted, during 2004, a total compensation package comprised of base salary, bonus, stock option awards and key employee retention programs. Key elements of the compensation philosophy are:

We pay competitive salaries based upon salaries paid by leading medical device companies with which Novoste competes for talent.

We maintain annual incentive opportunities sufficient to provide motivation to achieve specific operating goals and to generate rewards that bring total compensation to competitive levels.

We attempt to provide significant equity-based incentives for executives and other key employees to insure that individuals are motivated over the longer term to respond to our business challenges and opportunities as owners and not just employees.

We attempt to provide incentives for key employees to continue employment with the company in the periods of business uncertainty and changes in the company's strategic direction and potential continued employment for the executives.

We attempt through review and analysis of industry and peer group compensation data and surveys relating to similarly situated companies, to provide, with regard to all elements of our compensation programs, compensation and incentives to executives and other key employees that are competitive and designed to retain and motivate those individuals.

### *Compensation Program*

Our executive compensation program during 2004 was intended to retain and motivate executive officers consistent with the philosophy set forth above. The committee considers the means for accomplishing the objectives and the components of compensation programs individually, as well as collectively, in determining the total compensation for executive officers.

*Base salary.* Each year the committee establishes base salaries for individual executive officers based upon industry and peer group surveys, responsibilities, scope and complexity of each position, and performance judgments as to each individual's past and expected future contributions.

The committee reviews with the Chief Executive Officer and approves, with appropriate modifications, an annual base salary plan for our executive officers other than the Chief Executive Officer. The committee reviews and fixes the base salary of the Chief Executive Officer based on similar competitive compensation data and the committee's assessment of his past performance and the committee's expectation as to his future contributions in leading Novoste.

*Annual cash (short-term) incentives.* We established a cash incentive bonus plan for 2004 based upon achievement of certain goals and objectives during the fiscal year, which were tied to success in establishing our strategic direction and protection of shareholder value in our company. Target annual bonus awards are established for executive officers based upon peer group surveys and range from 30% to 50% of an executive's salary. Each officer who served in an executive capacity during and at the end of 2004 received a bonus for such service. The compensation committee determined that the executive management had achieved 70% of the 2004 goals established in the bonus plan and bonuses were paid accordingly.

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*Equity based incentive compensation.* Our primary long-term incentive program consists of our employee stock option plan. This stock option plan generally utilizes a four-year vesting period (although some stock options granted to key executives contained performance-based criteria or accelerated vesting features) to encourage key executive officers to continue employment with us. Through stock options grants, executives receive significant equity incentives to build long-term shareholder value. With respect to stock options, the exercise price of such stock options granted under the stock option plans is 100% of the fair market value of the underlying stock on the date of grant. Employees receive value from these grants only if our common stock appreciates over the long term. The diminution in our business and the uncertainties in our strategic direction has, by and large, diminished the long-term incentive value of such plans.

*Compensation of Chief Executive Officer.* At the committee's request, the total compensation of Mr. Novak, our President and Chief Executive Officer, was analyzed by a compensation consultant in January 2004. The report stated that while Mr. Novak's target bonus potential was low compared to the chief executive officers of other comparable medical device companies, his base salary and base salary, combined with his target bonus, fell within the 75<sup>th</sup> percentile of peer companies. The report stated that without additional long-term incentives, Mr. Novak's total direct compensation would fall below the median level for peer companies. As a result of the analysis and survey data received, the committee increased Mr. Novak's target bonus potential under the 2004 Corporate Bonus Incentive Plan from 40% of his annual salary to 50% of his annual salary. Additionally, the committee provided Mr. Novak additional long-term incentives under the 2004 Corporate Bonus Incentive Plan.

In June, 2004, the committee reviewed Mr. Novak's base salary compensation. Industry specific compensation data was obtained from a national compensation specialist's survey results stating that median 2004 merit increases were 4%. As a result, Mr. Novak's base salary was increased 3.9% by the committee on June 14, 2004.

*Key employee retention plans.* In 2004, the committee provided to certain key employees, including our executive officers, a Key Employee Retention Plan, which established a bonus for certain key employees if they remained in our employ through December 31, 2004 and through March 31, 2005. The Key Employee Retention Plan was for the purpose of retaining the services of executives during the periods of uncertainty as to future employment opportunities with our company.

*Establishment of rabbi trust.* Due to the possibility of a transaction which would alter the strategic direction, ownership or control of Novoste, the committee recommended to our board of directors, and our board of directors authorized, the establishment of a rabbi trust for the protection of certain elements of the compensation plans for our officers and other employees. The committee recommended, and the board approved, the contribution of amounts to the trust that would protect key employee retention and other bonus payments, severance payments and other benefits that would be paid to executives at the time of their termination.

### *Stock Option and Compensation Committee*

Stephen I. Shapiro, Chairman

J. Stephen Holmes

Judy Lindstrom

### *Compensation of Directors*

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Currently, directors who are also our employees 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.



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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 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 quarterly 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.

If the merger is completed, we expect that future compensation of members of the board of directors of the combined company will be as described in *Approval of Issuance of Shares in the ONI Merger*, *Interests of Certain Novoste and ONI Persons in the Merger*, and *Board Compensation*.

### ***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 us (or any of our subsidiaries), and no compensation committee interlocks existed during fiscal year 2004.

### ***Certain Relationships and Related Party Transactions***

We have adopted a policy that all transactions between us and our officers, directors, principal shareholders and their affiliates will be on terms no less favorable to us than could be obtained by us from unrelated third parties, and will be approved by our audit committee.

In December 2002, our audit committee reviewed and approved a distribution agreement between Novoste and Orbus Medical Technologies, Inc. The agreement provided for distribution of Orbus' products in Germany by Novoste. Alfred J. Novak, our president and chief executive officer, formerly served as chairman of the board of directors of Orbus and both Mr. Novak and members of his family had equity investments in Orbus. The audit committee undertook a full review of the terms of the agreement and determined the agreement was advantageous to Novoste and that it was no less favorable than could be obtained from an unrelated third party.

During 2004, Novoste purchased \$119,000 of product from Orbus. As of December 31, 2004 and 2003, Novoste had prepaid \$60,000 and \$169,000, respectively, for future product purchases and had \$169,000 and \$341,000, respectively, in inventory. In the years ending December 31, 2004 and 2003, Novoste had net sales of \$430,000 and \$620,000, respectively, 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 ceased distributing Orbus product during the first quarter of 2005.



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**STOCK PERFORMANCE GRAPH**

The following graph compares the percentage change in the cumulative total shareholder return on our common stock during the period from December 31, 1999, the last trading day before our 2000 fiscal year, through December 31, 2004, with the cumulative total return of the Nasdaq Market Index U.S. Companies and the Nasdaq Medical Equipment Index. In prior years, we included in this stock performance graph the JP Morgan Hambrecht & Quist Health Care Excluding Biotechnology Index. However, the JP Morgan Hambrecht & Quist Health Care Excluding Biotechnology Index ceased to be available during fiscal year 2002. Therefore, we have included the Nasdaq Medical Equipment Index in this stock performance graph. The comparison assumes \$100 was invested on December 31, 1999 in our common stock and in each of the foregoing indices and assumes any dividends were reinvested. The performance shown is not necessarily indicative of future performance.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

AMONG NOVOSTE CORPORATION, THE NASDAQ STOCK MARKET (U.S.) INDEX

AND THE NASDAQ MEDICAL EQUIPMENT INDEX

\* \$100 invested on 12/31/99 in stock or index-

including reinvestment of dividends.

Fiscal year ending December 31.

**Table of Contents****PRINCIPAL HOLDERS OF NOVOSTE COMMON STOCK**

The following table provides information as of the record date 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.

<u>Name of Beneficial Owner</u>	<u>Beneficial Ownership</u>	
	<u>Shares</u>	<u>Percentage</u>
Steel Partners II, L.P. and affiliated entities (1) 590 Madison Avenue, 32nd Floor New York, New York 10022	2,433,207	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%

- (1) Information obtained from Schedule 13D/A filed with the SEC by Steel Partners II, L.P. and Steel Partners, L.L.C. on April 15, 2005. 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 Steel Partners L.L.C., 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 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 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.

**Table of Contents****SECURITY OWNERSHIP OF NOVOSTE MANAGEMENT**

The following table provides information as of the record date 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 above under Executive Compensation and Other Information, and (3) all executive officers and directors as a group.

Name	Shares	Options	Total	
			Beneficial Ownership	Percentage (1)
Thomas D. Weldon (2)	178,770	139,000	317,770	1.9%
Alfred J. Novak		446,525	446,525	2.7%
Charles E. Larsen	311,161	35,000	346,161	2.1%
William E. Whitmer	9,000	40,000	49,000	*
Stephen I. Shapiro	4,213	35,000	39,213	*
J. Stephen Holmes		35,000	35,000	*
Judy Lindstrom		35,000	35,000	*
Daniel G. Hall	3,000	116,369	119,369	*
Robert N. Wood, Jr. (3)	1,018		1,018	*
Andrew M. Green (3)	228		228	*
Adam G. Lowe (3)				*
All executive officers and directors as a group (9) persons	506,144	934,994	1,441,138	8.3%

(\*) Less than 1%.

- (1) Applicable percentage of ownership as of the record date is based upon 16,334,780 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 of the record date 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 that percentage may differ for each shareholder.
- (2) Includes 2,500 shares held in trust for the benefit of Mr. Weldon's son, 2,500 shares held by Mr. Weldon as custodian for his nephew, 39,668 shares held by Mr. Weldon's spouse and 67,571 shares held by The Weldon Foundation, Inc., a Florida not-for-profit corporation in which Mr. Weldon is a director. Mr. Weldon disclaims beneficial ownership of all shares held by The Weldon Foundation, Inc.
- (3) This executive officer ceased employment with Novoste between January 1, 2005 and the record date and his beneficial ownership is not reflected in the line entitled All executive officers and directors as a group.

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**AUDIT COMMITTEE MATTERS**

Our audit committee has selected the firm of Ernst & Young LLP, independent registered public accounting firm, to serve as our independent auditors for the year ending December 31, 2005. Ernst & Young LLP has served as our independent auditors since 1992. We understand that representatives of Ernst & Young LLP will attend the special meeting, will have the opportunity to make a statement if they desire to do so and will also be available to respond to appropriate questions from the shareholders.

The audit committee has the responsibility for selecting our independent auditors and may terminate the engagement of Ernst & Young LLP as our independent auditors without the approval of the shareholders whenever the audit committee deems termination necessary or appropriate.

The work performed by Ernst & Young LLP during 2003 and 2004 and the related fees are stated below.

*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 our quarterly reports on Form 10-Q, and statutory audits required internationally.

*Audit-Related Fees*

Fees for audit-related services totaled \$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.

*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.

*All Other Fees*

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

The audit committee approves, in advance, the provision by Ernst & Young LLP 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 LLP throughout the year. The audit committee reviews both audit and non-audit services performed by Ernst & Young LLP as well as fees charged by Ernst & Young LLP for its services. In engaging Ernst & Young LLP for the services described above, the audit committee considered whether the provision of these services was compatible with maintaining Ernst & Young LLP's independence.

#### **Report of the Audit Committee**

The audit committee of our board of directors is composed of the following non-employee directors: William E. Whitmer, the Chairman, J. Stephen Holmes, and Judy Lindstrom. The audit committee is responsible for assisting the board of directors in its oversight of the integrity of our consolidated financial statements, the qualifications and independence of our independent auditors, and our internal financial and accounting controls. The audit committee has the sole authority and responsibility to select, evaluate and, when appropriate, replace our independent auditors. None of the current members of the audit committee are employees of Novoste and our board of directors has determined that each member of the audit committee is independent (as independence is defined in the listing standards of the Nasdaq Stock Market currently in effect). The board of directors has

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determined that Mr. Whitmer is an audit committee financial expert as that term is defined in Item 401(h) of Regulation S-K.

Management is responsible for the financial reporting process, including the system of internal controls, and for the preparation of consolidated financial statements in accordance with generally accepted accounting principles. Our independent auditors are responsible for auditing those financial statements and expressing an opinion as to their conformity with generally accepted accounting principles. The audit committee's responsibility is to oversee and review these processes. The audit committee is not, however, professionally engaged in the practice of accounting or auditing and does not provide any expert or other special assurance as to such financial statements concerning compliance with laws, regulations or generally accepted accounting principles or as to auditor independence. The audit committee relies, without independent verification, on the information provided to it and on the representations made by management and the independent auditors. A written charter governing the functions of the audit committee was revised and approved by the board of directors on February 11, 2004. A copy of the audit committee's current charter was attached to our 2004 proxy statement as Appendix A.

In this context, the audit committee has met and held discussions with management and the independent accountants. Management represented to the audit committee that our consolidated financial statements were prepared in accordance with generally accepted accounting principles, and the audit committee has reviewed and discussed the consolidated financial statements with management and the independent accountants. The audit committee discussed with the independent accountants matters required to be discussed by Statement on Auditing Standards No. 61 (Communications with Audit Committees).

The audit committee also reviewed the process by we would assure compliance with Section 404 of the Sarbanes-Oxley Act relating to certification of the systems of internal controls and procedures. We used the services of an outside accounting firm to assist with the Section 404 compliance program. These services were approved by the audit committee, and the committee received periodic reports on the project from management and the accounting firm retained for this purpose.

Our independent accountants also provided to the audit committee the written disclosure and the letter from the independent accountants required by Independence Standards Board Standard No. 1 (Independence Discussions with Audit Committees), and the audit committee discussed with the independent accountants the accounting firm's independence. The committee also considered whether non-audit services provided by the independent accountants during the last fiscal year were compatible with maintaining the independent accountants independence.

Based upon the audit committee's discussion with management and the independent accountants and the audit committee's review of the representations of management and the report of the independent accountants to the audit committee, the audit committee recommended to the board of directors that the audited consolidated financial statements be included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004 filed with the SEC.

*Audit Committee*

William E. Whitmer, Chairman

J. Stephen Holmes

Judy Lindstrom





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**THE ADJOURNMENT PROPOSAL**

**(Proposal 5)**

We are asking our shareholders to authorize the holder of the proxy solicited by our board of directors to vote in favor of adjourning the special meeting to a future date in order to enable our board of directors to solicit additional proxies in favor of the share issuance and the two proposed amendments to our articles of incorporation if we present such a proposal.

If at the special meeting the number of shares of our common stock voting in favor of the share issuance and the two proposed amendments to our articles of incorporation is insufficient to approve any of these proposals, the chairperson of the meeting may move to adjourn the special meeting to enable us to solicit additional proxies in favor of these proposals. If such a proposal is made at the meeting, the proxy holder will only be able to vote in favor of this proposal the shares for which it has received a valid proxy indicating that it has the authority to vote in favor of an adjournment proposal.

**Vote Required**

The approval of this proposal requires that the number of votes cast by the shareholders at the special meeting in favor of the proposal exceed the number of votes cast against the proposal. Only shares that are voted FOR or AGAINST the proposal will be counted towards the vote requirement. Thus, shares represented at the meeting that are marked ABSTAIN, and broker non-votes, if any, will not be counted towards the vote requirement. Additionally, if you do not complete and return a proxy card and do not vote in person, there will be no effect on the outcome of the vote.

**Recommendation of our Board of Directors**

Our board of directors recommends that our shareholders vote in favor of proposal 5.

**OUR BOARD OF DIRECTORS RECOMMENDS A VOTE FOR PROPOSAL 5.**

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**SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE**

Section 16 of the Securities Exchange Act of 1934, as amended, requires that officers, directors and holders of more than 10% of our common stock file reports of their trading in our equity securities with the SEC. Based on a review of Section 16 forms filed by the reporting persons with respect to the last fiscal year, we believe that all reporting persons complied with all applicable Section 16 requirements for Form 3, Form 4 and Form 5 filings with respect to 2004.

**OTHER BUSINESS**

We have no other matter that may properly come before the special meeting in lieu of an annual meeting. However, if any other matter requiring a vote of shareholders should arise, it is the intention of the persons named in the enclosed proxy card to vote the proxy in accordance with their best judgment.

All shareholder proposals to be considered for inclusion in next year's annual meeting proxy statement pursuant to the shareholder proposal rules of the SEC must be submitted in writing to Corporate Secretary, Novoste Corporation, 4350 International Boulevard, Norcross, Georgia, 30093 (or, if the merger is completed, Corporate Secretary, ONI Medical Systems Inc., 301 Ballardvale Street, Suite 4, Wilmington, MA 01887) by April 6, 2006. Any such proposal received after that date will be considered untimely and may be excluded from the proxy materials.

In the event that the 2006 annual meeting of shareholders is changed by more than 30 days from the date of this year's special meeting in lieu of an annual meeting, the deadline for providing us notice under the SEC rules will be a reasonable time before we begin to print and mail our proxy soliciting materials. It is currently expected that the 2006 annual meeting will be held in the spring of 2006.

Our by-laws establish an advance notice procedure with regard to proposals (including director nominations) that shareholders otherwise desire to introduce at the annual meeting without inclusion in our proxy statement for that meeting. Written notice of such shareholder proposals for our next annual meeting must be received by our Corporate Secretary at our principal executive offices not later than June 16, 2006 and must not have been received earlier than May 17, 2006 in order to be considered timely, and must contain specified information concerning the matters proposed to be brought before such meeting and concerning the shareholder proposing such matters. The matters proposed to be brought before the meeting also must be proper matters for shareholder action. In the event that the 2006 annual meeting of shareholders is more than 30 days before or more than 60 days after September 14, 2006 (the first anniversary of our 2005 special meeting in lieu of an annual meeting), written notice of such shareholder proposals must be received by the Corporate Secretary not later than the tenth day following the earlier of (a) the day on which public announcement of the date of the 2006 annual meeting is first made by us or (b) the date notice of the annual meeting was mailed to shareholders.

**IMPORTANT NOTICE REGARDING DELIVERY OF SHAREHOLDER DOCUMENTS**

In accordance with notices sent to shareholders sharing a single address, we are sending only one proxy statement to that address unless we received contrary instructions from any shareholder at that address. This householding practice reduces our printing and postage costs. Shareholders may request or discontinue householding, or may request a separate copy of the proxy statement as follows:

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Record shareholders wishing to discontinue or begin householding, or any record shareholder residing at a householded address wanting to request delivery of a copy of the 2004 Annual Report on Form 10-K or proxy statement, should contact our transfer agent, American Stock Transfer and Trust Company, at 1-877-777-0800 or [www.amstock.com](http://www.amstock.com), or may write to them at 6201 15<sup>th</sup> Avenue, Brooklyn, NY 11219.

Shareholders owning their shares through a bank, broker or other holder of record who wish to either discontinue or begin householding should contact their record holder.

Any householded shareholder may request prompt delivery of a copy of the proxy statement by contacting us at 770-810-3149 or may write to our investor relations department, 4350 International Boulevard, Norcross, Georgia 30093.

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**ELECTRONIC ACCESS TO ANNUAL MEETING MATERIALS**

This proxy statement is available on our website at [www.novoste.com](http://www.novoste.com). Your consent to access these documents over the Internet can save us postage and printing expense. If you consent, you will receive notice next year when these documents are available with instructions on how to view them and submit voting instructions. If you are a shareholder of record, you may sign up for this service by contacting American Stock Transfer and Trust Company at [www.amstock.com](http://www.amstock.com). If you hold your shares through a bank, broker or other holder of record, you should contact the record holder for information regarding electronic delivery of materials. Your consent to electronic delivery will remain in effect until you revoke it. If you choose electronic delivery, you may incur costs, such as telephone and Internet access charges, for which you will be responsible.

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-732-0330 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 us file electronically with the SEC. The SEC's website is located at [www.sec.gov](http://www.sec.gov).

We make available, free of charge through our website at [www.novoste.com](http://www.novoste.com), 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, as soon as reasonably practicable after the material is electronically filed with, or furnished to, the SEC. The information on our website is not incorporated by reference into this proxy statement.

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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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**Table of Contents****NOVOSTE CORPORATION****CONSOLIDATED BALANCE SHEETS**

(in thousands, except number of shares data)

	<b>December 31, 2004</b>	<b>December 31, 2003</b>
<b>ASSETS</b>		
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
	<u>33,001</u>	<u>47,527</u>
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
	<u>1</u>	<u>579</u>
Total assets	<u>\$ 33,702</u>	<u>\$ 61,407</u>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,511	\$ 1,492
Accrued expenses	3,823	6,483
Unearned revenue	1,914	188
	<u>7,248</u>	<u>8,163</u>
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)
	<u>26,454</u>	<u>53,244</u>
Total shareholders' equity	26,454	53,244
Total liabilities and shareholders' equity	<u>\$ 33,702</u>	<u>\$ 61,407</u>

See accompanying notes.



**Table of Contents****NOVOSTE CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS****(in thousands, except per-share data)**

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
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.

**Table of Contents****NOVOSTE CORPORATION****CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY**

(in thousands, except per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock		Unearned Compensation	Total
	Shares	Amount				Shares	Amount		
Balance at January 1, 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)
<b>Total Comprehensive loss</b>									<b>(12,453)</b>
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 (Continued)

(in thousands, except per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Treasury Stock		Unearned Compensation	Total
	Shares	Amount		Accumulated Deficit	Shares	Amount			
Exercise of stock options at \$3.20 to \$6.65	4	\$	\$ 292	\$	\$	101	\$ 382	\$	\$ 674
Issuance of stock under Employee Stock Purchase Plan, 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)
<b>Total Comprehensive loss</b>									<b>(325)</b>
Balance at December 31, 2003	16,372	\$ 164	\$ 187,880	\$ 733	\$ (135,302)	(43)	\$ (172)	\$ (59)	\$ 53,244

See accompanying notes.

**Table of Contents****NOVOSTE CORPORATION****CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (Continued)**

(in thousands, except per share amounts)

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Treasury Stock</u>		<u>Unearned Compensation</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>				<u>Shares</u>	<u>Amount</u>		
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)
<b>Total Comprehensive loss</b>									<b>(26,828)</b>
Balance at December 31, 2004	16,378	\$ 164	\$ 187,894	\$ 826	\$ (162,223)	(43)	\$ (172)	\$ (35)	\$ 26,454

See accompanying notes.

**Table of Contents****NOVOSTE CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Year Ended December 31,		
	2004	2003	2002
<b>Cash flows from operating activities:</b>			
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)
<b>Net cash (used in) provided by operating activities</b>	<b>(6,300)</b>	<b>9,192</b>	<b>10,709</b>
<b>Cash flows from investing activities:</b>			
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)
<b>Net cash (used in) provided by investing activities</b>	<b>(7,876)</b>	<b>1,142</b>	<b>5,183</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock	15	768	636
Purchase of treasury stock		(109)	(616)
Repayment of capital lease obligations		(183)	(270)
<b>Net cash provided by financing activities</b>	<b>15</b>	<b>476</b>	<b>(250)</b>
Effect of exchange rate changes on cash	66	439	408
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(14,095)</b>	<b>11,249</b>	<b>16,050</b>
Cash and equivalents at beginning of year	33,177	21,928	5,878
<b>Cash and cash equivalents at end of year</b>	<b>\$ 19,082</b>	<b>\$ 33,177</b>	<b>\$ 21,928</b>
<b>Supplemental disclosure of cash flow information:</b>			



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

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**NOVOSTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

**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.

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**NOVOSTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

**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.

**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 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).

<u>Change</u>	<u>Increase (Decrease) Cost of sales</u>
	<u>2002</u>
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
<b>Net impact</b>	<b>\$ 3,639</b>
<b>Net effect on loss per share</b>	<b>\$ (0.22)</b>

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,

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**NOVOSTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Accounting for Stock Issued to Employees* (APB 25) and related interpretations. Under (APB 25), no compensation expense is recognized for stock option grants to employees for which the terms are fixed. The Company grants stock options generally for a fixed number of shares to employees, directors, consultants and independent contractors with an exercise price equal to the fair market value of the shares at the date of grant. Compensation expense is recognized for increases in the estimated fair value of common stock for any stock options with variable terms.

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

In December 2002, the Financial Accounting Standards Board 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.

**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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.

**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Available-for-Sale Investments**

Available-for-sale investments at December 31, 2004 were as follows (in thousands):

	<u>Adjusted Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Loss</u>	<u>Estimated Fair Value</u>
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
<b>Total available-for-sale investments</b>	<b>26,549</b>	<b>\$</b>	<b>\$ (8)</b>	<b>\$ 26,541</b>
Less amounts classified as cash equivalents	(16,563)			
Unrecognized net loss	(8)			
	<u>\$ 9,978</u>			

Available for Sale Investments at December 31, 2003 were as follows (in thousands):

	<u>Adjusted Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Loss</u>	<u>Estimated Fair Value</u>
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
<b>Total available-for-sale investments</b>	<b>28,590</b>	<b>\$ 2</b>	<b>\$ (8)</b>	<b>\$ 28,584</b>
Less amounts classified as cash equivalents	(22,359)			
Unrecognized net loss	(6)			

\$ 6,225

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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):

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

### 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.



**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

**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):

	<b>December 31,</b>	<b>December 31,</b>
	<b>2004</b>	<b>2003</b>
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
	<hr/>	<hr/>
Property and equipment, gross	8,957	16,757
Less: Accumulated depreciation and amortization	(8,257)	(9,760)
	<hr/>	<hr/>
Property and equipment, net	\$ 700	\$ 6,997
	<hr/>	<hr/>

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).

**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

**6. RADIATION AND TRANSFER DEVICES**

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

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

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

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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).

**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. ACCRUED EXPENSES**

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

	December 31,	December 31,
	2004	2003
	<u>          </u>	<u>          </u>
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
	<u>          </u>	<u>          </u>
	<u>\$ 3,823</u>	<u>\$ 6,483</u>

**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.

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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.

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**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****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,	December 31,
	2004	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
	<u>39,679</u>	<u>59,750</u>
Valuation allowance for deferred income tax assets	(39,679)	(59,750)
	<u>\$</u>	<u>\$</u>
Net deferred income tax assets	<u>\$</u>	<u>\$</u>

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 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

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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

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**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 expire 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):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
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
	<u>\$</u>	<u>\$</u>	<u>\$</u>

**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 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  $1\frac{1}{100}$ <sup>th</sup> (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.

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**NOVOSTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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 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.

**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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:

Range Of Exercise Prices	Number Of Shares	Options Outstanding		Options Exercisable	
		Weighted Average Remaining Contractual	Weighted Average	Number Exercisable	Weighted Average Exercise

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		<u>Life (Years)</u>	<u>Exercise Price Of</u>			<u>Price</u>
		<u>Options Outstanding</u>				
\$ 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
		<u>3,285,304</u>	7.59	7.38	<u>1,732,555</u>	10.54

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.

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**NOVOSTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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**

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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 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.

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**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****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
	<hr/>
	\$ 414
	<hr/>

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.



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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 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

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**NOVOSTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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value of the 5.0F systems that are equipped to be used with 30mm and 40mm radiation source trains. Based on this evaluation, the Company determined that the 5.0F transfer devices and the related radiation source trains, with a carrying amount of \$8,593,000, were impaired and wrote them down by \$5,065,000, to their estimated fair value of \$3,528,000, and accrued \$1,835,000 for related contract commitments, resulting in impairment and other related charges of \$6,900,000 for the second quarter of 2002. Fair value was based on expected future net cash flows to be generated by the transfer devices and radiation source trains during their remaining service lives, discounted at the risk-free rate of interest. The remaining fair value 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.

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**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
	—	—
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	<b>\$ 676</b>	<b>\$ 565</b>
	—	—

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Expense reported in:		
Cost of Sales	\$ 274	\$
	<u>          </u>	<u>          </u>
Operating Expenses	\$ 402	\$ 565
	<u>          </u>	<u>          </u>

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**Table of Contents****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):

<u>Net sales</u>	<u>United States</u>	<u>Rest of World</u>	<u>Consolidated</u>
2004	\$ 19,391	\$ 3,877	\$ 23,268
2003	57,915	4,986	62,901
2002	64,746	4,284	69,030
	<b>United</b>	<b>Rest of</b>	
<u>Net income (loss)</u>	<u>States</u>	<u>World</u>	<u>Consolidated</u>
2004	\$ (26,293)	\$ (628)	\$ (26,921)
2003	(932)	64	(868)
2002	(8,109)	(4,942)	(13,051)

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<b>Long-lived assets</b>	<b>United States</b>	<b>Rest of World</b>	<b>Consolidated</b>
2004	\$ 700	\$ 1,191	\$ 700
2003	12,689	1,191	13,880
<b>Total assets</b>			
<b>2004</b>	<b>United States</b>	<b>Rest of World</b>	<b>Consolidated</b>
2004	\$ 31,794	\$ 1,908	\$ 33,702
2003	57,264	4,143	61,407

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**Table of Contents****NOVOSTE CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****19. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

(In thousands, except per share amounts)

	(In thousands, except per share amounts)			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	Ended	Ended	Ended	Ended
	March 31	June 30	September 30	December 31
<b>Fiscal 2004</b>				
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)
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	Ended	Ended	Ended	Ended
	March 31	June 30	September 30	December 31
<b>Fiscal 2003</b>				
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**



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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		Deduction	Balance
	Beginning of	Charged to	From	End of
	Period	Operations	Reserve	Period
<b><i>Fiscal Year 2004</i></b>				
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
<b><i>Fiscal Year 2003</i></b>				
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)	
<b><i>Fiscal Year 2002</i></b>				
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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## NOVOSTE CORPORATION

## UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per-share data)

	Three Months Ended	
	March 31,	
	2005	2004
Net sales	\$ 3,413	\$ 7,025
Cost of sales	4,118	3,953
Gross margin (loss)	(705)	3,072
Operating expenses:		
Research and development	434	2,475
Sales and marketing	2,702	3,489
General and administrative	2,878	1,800
Total operating expenses	6,014	7,764
Loss from operations	(6,719)	(4,692)
Interest income	140	87
Other income (expense)	25	(9)
Total other income	165	78
Net loss	\$ (6,554)	\$ (4,614)
Net loss per share Basic and Diluted	\$ (0.40)	\$ (0.28)
Weighted average shares outstanding Basic and Diluted	16,335	16,331

See accompanying notes.

**Table of Contents****NOVOSTE CORPORATION****CONSOLIDATED BALANCE SHEETS**

(in thousands, except number of shares data)

	<b>March 31,</b>	<b>December 31,</b>
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 20,559	\$ 19,082
Short-term investments	4,103	9,978
Accounts receivable, net of allowance of \$202 and \$125, respectively	894	1,928
Inventory, net	203	1,206
Assets held for sale	462	
Prepaid expenses and other current assets	634	807
	<u>          </u>	<u>          </u>
Total current assets	26,855	33,001
Property and equipment, net	188	700
Other assets		1
	<u>          </u>	<u>          </u>
Total assets	\$ 27,043	\$ 33,702
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities		
Accounts payable	\$ 1,137	\$ 1,511
Accrued expenses	4,755	3,823
Unearned revenue	1,345	1,914
	<u>          </u>	<u>          </u>
Total current liabilities	7,237	7,248
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 shares issued	164	164
Additional paid-in capital	187,848	187,894
Accumulated other comprehensive income	744	826
Accumulated deficit	(168,777)	(162,223)
Treasury stock, at cost, 42,929 shares	(172)	(172)
Unearned compensation	(1)	(35)
	<u>          </u>	<u>          </u>
Total shareholders' equity	19,806	26,454
	<u>          </u>	<u>          </u>
Total liabilities and shareholders' equity	\$ 27,043	\$ 33,702
	<u>          </u>	<u>          </u>

See accompanying notes.



**Table of Contents****NOVOSTE CORPORATION****UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Three Months Ended	
	March 31,	
	2005	2004
Cash flows from operating activities:		
Net loss	\$ (6,554)	\$ (4,614)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment		637
Amortization of capitalized disposal costs	33	33
Stock based compensation expense	(12)	26
Depreciation of radiation and transfer devices		1,099
Provision for doubtful accounts	84	(55)
Changes in assets and liabilities:		
Accounts receivable	930	2,361
Inventory	993	(184)
Prepaid expenses and other current assets	152	111
Other assets	22	164
Accounts payable	(342)	(439)
Accrued expenses	935	(1,454)
Unearned revenue	(568)	(46)
	<u>(4,327)</u>	<u>(2,361)</u>
Net cash used in operating activities	(4,327)	(2,361)
Cash flows from investing activities:		
Maturity/sale of short-term investments	7,158	3,504
Purchase of short-term investments	(1,283)	(2,035)
Purchase of property and equipment, net		(152)
Purchase of radiation and transfer devices		(573)
	<u>5,875</u>	<u>744</u>
Net cash provided by investing activities	5,875	744
Cash flows from financing activities:		
Proceeds from issuance of common stock		7
		<u>7</u>
Net cash provided by financing activities		7
Effect of exchange rate changes on cash	(71)	(73)
	<u>1,477</u>	<u>(1,683)</u>
Net increase (decrease) in cash and cash equivalents	1,477	(1,683)
Cash and equivalents at beginning of period	19,082	33,177
	<u>\$ 20,559</u>	<u>\$ 31,494</u>
Cash and cash equivalents at end of period	\$ 20,559	\$ 31,494

See accompanying notes.



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**NOVOSTE CORPORATION**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**MARCH 31, 2005**

**NOTE 1. BASIS OF PRESENTATION**

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and in accordance with instructions to Article 10 of Regulation S-X. Accordingly, such consolidated financial statements do not include all of the information and disclosures required by accounting principles generally accepted in the United States for complete financial statements. All normal and recurring adjustments considered necessary for a fair presentation of Novoste's financial results and condition have been included.

The operating results of the interim periods presented are not necessarily indicative of the results to be achieved for the year ending December 31, 2005. The accompanying unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2004, included in Novoste's 2004 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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

On February 22, 2005, Novoste announced that the Board of Directors had determined that its vascular brachytherapy (VBT) business, which is its only business line, is no longer viable and, as a result, has authorized a staged wind-down of the business. As described in the notes that follow, assets have been stated at estimated net realizable value and accruals have been recorded to reflect the business assumptions of the wind-down in accordance with FAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*.

**NOTE 2. SIGNIFICANT ACCOUNTING POLICIES**

Novoste's significant accounting policies are included in the audited financial statements and notes thereto for the year ended December 31, 2004 included in Novoste's 2004 Annual Report on Form 10-K (2004 10-K) filed with the Securities and Exchange Commission. The items below supplement the information presented in the 2004 10-K.



**Table of Contents****NOVOSTE CORPORATION****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****MARCH 31, 2005***Stock Options*

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
Net loss, as reported	\$ (6,554)	\$ (4,614)
Add: Total stock-based employee compensation expense (income) included in net loss	(12)	26
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(197)	(576)
<b>Pro forma net loss</b>	<b>\$ (6,763)</b>	<b>\$ (5,164)</b>
<b>Loss per share (Basic and Diluted):</b>		
As reported	\$ (0.40)	\$ (0.28)
<b>Pro forma</b>	<b>\$ (0.41)</b>	<b>\$ (0.32)</b>

In December 2004, the FASB issued FASB Statement No. 123(R), *Share Based Payment*. 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. All public companies must use either the modified prospective or the modified retrospective transition method.

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The Company previously disclosed that it planned to adopt SFAS 123(R) on July 1, 2005. Pursuant to an SEC Amendment to Regulation S-X effective April 21, 2005, the revised date for adopting SFAS 123(R) is the first interim reporting period of a registrant's first fiscal year beginning on or after June 15, 2005. As a result, the Company now plans to adopt SFAS 123(R) on January 1, 2006. As of March 31, 2005, we have not determined the effect that the adoption of SFAS 123(R) will have on our financial position and results of operations or the method under which we will apply SFAS 123(R).

### *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. Recoverability of assets to be held and used is determined based on the carrying value of an asset exceeding the future undiscounted net cash flow expected to be generated by the asset. If an asset is not recoverable, impairment is measured by the excess of the discounted future cash flows over the carrying value of the asset (see also Note 14 to the unaudited consolidated financial statements).

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**NOVOSTE CORPORATION**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**MARCH 31, 2005**

*Assets Held for Sale*

Following the announcement of a staged wind-down and subsequent determination as of the timing thereof, Novoste committed to a plan for the sale of certain assets in accordance with the wind-down plan. The plan includes actively identifying and seeking buyers for these assets. In accordance with the provisions of SFAS 144, assets held for sale are stated at estimated net realizable value and depreciation on these assets has been suspended (see also Note 6 to the unaudited consolidated financial statements).

*Employment Termination costs*

As part of the wind-down plan, Novoste has provided incentives to certain employees to remain with the Company to manage the wind-down. To receive these incentive payments, they are required to remain with the Company until their employment is terminated. Novoste accounts for these termination benefits in accordance with FAS 146, *Accounting for Costs Associated with Exit or Disposal Activities* (see also Note 15 to the unaudited consolidated financial statements).

**NOTE 3. CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS**

Cash equivalents are comprised of certain highly liquid investments acquired with maturities of less than three months. In addition to cash equivalents, Novoste has investments in commercial paper and other securities that are classified as short-term. All securities are considered as available-for-sale and reported at fair value, with the unrealized gains and losses reported as a component of Other Comprehensive Income (Loss) on the consolidated statements of shareholders' equity (see Note 13 to the unaudited consolidated financial statements). The amortized cost of debt securities in this category, if significant, is adjusted for amortization and included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, of which there were none, would be included in interest income. Realized gains and losses are included in interest income and are determined on a specific identification basis. Interest and dividends on securities classified as available-for-sale are included in interest income.

**NOTE 4. ACCOUNTS RECEIVABLE**

Accounts receivable at March 31, 2005 and December 31, 2004 include receivables due from product sales and amounts due under lease and maintenance or service agreements with customers relating to radiation and transfer devices (see Note 7 to the unaudited consolidated financial statements). The carrying amounts reported in the consolidated balance sheets for accounts receivable approximate their fair value. Management records estimates of expected credit losses based on periodic credit evaluations of its customers' financial condition.

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
Accounts receivable, gross	\$ 1,096	\$ 2,053
Less: Provision for doubtful accounts	(202)	(125)
	<u>          </u>	<u>          </u>
Accounts receivable, net	<u>\$ 894</u>	<u>\$ 1,928</u>

There were no significant concentrations of credit risk at March 31, 2005.

**Table of Contents****NOVOSTE CORPORATION****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****MARCH 31, 2005****NOTE 5. INVENTORIES**

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
Raw materials	\$ 1,963	\$ 1,922
Work in process	79	133
Finished goods	691	871
	<u>          </u>	<u>          </u>
Inventory, gross	2,733	2,926
Less: Inventory reserve	(2,530)	(1,720)
	<u>          </u>	<u>          </u>
Inventory, net	<u>\$ 203</u>	<u>\$ 1,206</u>

An inventory reserve is established based on expected usage over the term of the wind-down. In this regard, all inventory in excess of estimated sales and service needs is fully reserved. For the quarter ended March 31, 2005, approximately \$837,000 of expenses was recorded in cost of sales for inventory estimated to be in excess of needs projected in the wind-down plan.

**NOTE 6. PROPERTY AND EQUIPMENT**

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
Furniture and fixtures	\$ 789	\$ 791
Office equipment	1,873	1,979
Laboratory equipment	533	553

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Leasehold improvements	542	542
Production equipment	5,051	5,092
	<u>          </u>	<u>          </u>
Property and equipment, gross	8,788	8,957
Less: Accumulated depreciation and amortization	(8,138)	(8,257)
Less: Assets held for sale	(462)	
	<u>          </u>	<u>          </u>
Property and equipment, net	\$ 188	\$ 700
	<u>          </u>	<u>          </u>

Included in the property plant and equipment is capitalized disposal costs of approximately \$188,000, which relates to the Company's obligation for decommissioning the radiation source train production facility.

During the fourth quarter of 2004, Novoste recorded an impairment charge to reflect the reduced carrying value of all assets that support the VBT business (see Note 14 to the unaudited consolidated financial statements).

*Assets Held For Sale*

Following the announcement of a staged wind-down of the Company's VBT business and subsequent determination as to the timing thereof, the Company committed to a plan to sell certain assets in accordance with the terms of the wind-down plan. Based on the provisions of SFAS 144, the Company determined that these

**Table of Contents****NOVOSTE CORPORATION****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****MARCH 31, 2005**

assets, valued at \$462,000 and included in the unaudited consolidated balance sheet, met the criteria for classification as held for sale at March 31, 2005. Assets held for sale at March 31, 2005 were comprised of property and equipment and are recorded at net realizable value.

**NOTE 7. RADIATION AND TRANSFER DEVICES**

Novoste retains ownership of the radiation source trains (RSTs) and transfer devices (TDs). Depreciation of the costs of these assets is taken over the estimated economic life using the straight-line method and is recorded in cost of sales. Depreciation begins at the time the Beta-Cath System is placed into service. Novoste classifies the annual agreements with Novoste's customers to license the use of radiation and transfer devices as operating leases. Income is recognized ratably over the length of the agreement. At March 31, 2005, unearned revenue under these agreements approximated \$1,345,000 compared to \$1,914,000 at December 31, 2004.

Radiation and transfer devices, stated at cost net of impairment, less accumulated depreciation, are comprised of the following (in thousands):

	<b>March 31,</b>	<b>December 31,</b>
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
Radiation and transfer devices, gross	\$ 10,889	\$ 14,977
Less: Accumulated depreciation	(10,889)	(14,977)
	<u>          </u>	<u>          </u>
Radiation and transfer devices, net	<u>\$</u>	<u>\$</u>

During the quarter ended December 31, 2004, Novoste concluded that these assets were fully impaired and recorded an impairment charge bringing their net book value to zero. During the first quarter of 2005, approximately 900 of the devices, with an acquired cost net of impairment of \$4,088,000, were decommissioned because they had no foreseeable use. These assets were fully depreciated, thus, there was no effect on net income for the three months ended March 31, 2005.

**NOTE 8. OTHER ASSETS**

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At March 31, 2005 other assets consist mainly of license agreements and other intangibles. On April 22, 2004, Novoste signed 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 in the United States and Canada. Under the terms of the agreement, during a six-month transition period beginning on April 22, 2004, Guidant and Novoste cooperated jointly to transition the Guidant customers to Novoste products for any customer that wished to continue vascular brachytherapy. Guidant discontinued 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 and agreed to pay Guidant an additional 5% on net sales to customers on the Guidant customer list that transition to Novoste's products for a period of six months after April 22, 2004. After this six-month transition period, Novoste pays 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. During the quarter ended December 31, 2004, Novoste concluded that these assets were fully impaired and recorded an impairment charge bringing the net book value to zero. No amortization expense was recorded during the quarter ended March 31, 2005.

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**Table of Contents****NOVOSTE CORPORATION****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****MARCH 31, 2005****NOTE 9. ACCRUED EXPENSES**

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
Salaries, wages and benefits	\$ 1,539	\$ 1,216
Purchase commitments	1,324	
Radiation and disposals	709	891
Operating expenses and royalties	363	433
Professional fees	535	892
Clinical trials	155	205
Due to customers	69	104
Sales and use taxes	61	82
	<u>          </u>	<u>          </u>
	<b>\$ 4,755</b>	<b>\$ 3,823</b>
	<u>          </u>	<u>          </u>

The accrued purchase commitments in the table above represent the present value of minimum payment obligation under a current supply contract (see Note 14 of the unaudited consolidated financial statements).

**NOTE 10. 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. 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 March 31, 2005. At March 31, 2005, the Company had \$75,000 in outstanding letters of credit, which are secured by a certificate of deposit.

**NOTE 11. SEGMENT INFORMATION**

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

The following is a summary of selected financial information by reportable segment as of, and for the three months ended, March 31, 2005 and 2004 (in thousands):

### Net sales

	<u>United States</u>	<u>Rest of World</u>	<u>Consolidated</u>
2005	\$ 2,323	\$ 1,090	\$ 3,413
2004	5,959	1,066	7,025

### Net loss

	<u>United States</u>	<u>Rest of World</u>	<u>Consolidated</u>
2005	\$ (6,552)	\$ (2)	\$ (6,554)
2004	(4,566)	(48)	(4,614)

**Table of Contents****NOVOSTE CORPORATION****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****MARCH 31, 2005**

## Long-lived assets

	<u>United States</u>	<u>Rest of World</u>	<u>Consolidated</u>
2005	\$ 114	\$ 74	\$ 188
2004	11,499	754	12,253

## Total assets

	<u>United States</u>	<u>Rest of World</u>	<u>Consolidated</u>
2005	\$ 25,050	\$ 1,993	\$ 27,043
2004	51,604	3,178	54,782

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

**NOTE 12. EARNINGS PER SHARE**

The following table sets forth the computation of basic and diluted earnings per share for the three months ended March 31, 2005 and 2004 (in thousands, except per-share data):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<u>2005</u>	<u>2004</u>
<b>Numerator:</b>		
Net loss	\$ (6,554)	\$ (4,614)
<b>Denominator:</b>		
Weighted-average shares outstanding	16,335	16,331
<b>Net loss per share:</b>		
Basic and Diluted	\$ (0.40)	\$ (0.28)

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The basic and diluted loss per share is computed based on the weighted average number of common shares outstanding. Weighted average shares outstanding, assuming dilution, includes the incremental shares that would be issued upon the assumed exercise of stock options. For the calculation of the three months ended March 31, 2005 and 2004, all stock options, representing approximately 2,778,000 and 2,928,000 shares of Novoste common stock, respectively, were excluded, as they would be anti-dilutive. Of these, approximately 2,778,000 and 1,847,000 shares had an exercise price higher than the average price of Novoste's common stock for the three-month periods ended March 31, 2005 and 2004, respectively.

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**Table of Contents****NOVOSTE CORPORATION****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****MARCH 31, 2005****NOTE 13. SHAREHOLDERS' EQUITY**

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
Shareholders' equity at beginning of period	\$ 26,454	\$ 53,244
Proceeds from exercise of stock options ranging from \$3.20 to \$6.65 per share		7
Amortization of unearned compensation		27
Amortization of fair market value of stock options to non employees	(5)	(4)
Cancellation of stock options to non employees	(7)	3
Comprehensive income:		
Unrealized gain on held-for-sale securities	3	
Translation adjustment	(85)	(93)
Net loss	(6,554)	(4,614)
<b>Total comprehensive loss</b>	<b>(6,636)</b>	<b>(4,707)</b>
Shareholders' equity at end of period	\$ 19,806	\$ 48,570

**NOTE 14. IMPAIRMENT AND OTHER CHARGES**

During the third quarter of 2004, Novoste suspended production of radiation source trains at its supplier, 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.

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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 and expensed in the functions where the assets were used. At December 31, 2004, 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 net realizable value.

In connection with changes in the Company's forecasted needs for radiation source trains resulting from the timing of the staged wind-down of the Company's VBT business, it is unlikely that additional radiation source trains will be purchased during the remaining life of the supply contract with AEA, which expires in September 2006. Under the agreement, Novoste is obligated to make minimum payments through the end of the contract. Given that Novoste will most likely not receive future economic benefit from these required payments, we have

**Table of Contents****NOVOSTE CORPORATION****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****MARCH 31, 2005**

accrued the present value of these contractual payments, which aggregate \$1,324,000, and included them in cost of sales for the quarter ended March 31, 2005.

**NOTE 15. EMPLOYMENT TERMINATION COSTS**

On February 22, 2005, Novoste announced that the Board of Directors had determined that its VBT business, which is its only business line, is no longer viable and, as a result, has authorized a staged wind-down of the business. The staged plan is necessary to maximize the value of the remaining assets of Novoste. In summary, the total of personnel related termination costs, which consist of severance pay, outplacement assistance and retention incentives, are expected to aggregate approximately \$4,407,000 through the execution of the wind-down plan which will be completed in late 2005. Approximately \$555,000 relate to personnel in Europe with the remaining applicable to U.S. operations.

During the quarter ended March 31, 2005, the Company eliminated approximately 50 positions and recorded expenses of \$1,451,000 related to the employees who left Novoste prior to March 31, 2005 and an additional \$950,000, which is a prorated portion of termination costs, related to the remaining employees who will manage the wind-down. The costs associated with terminated employees are included within operating expenses in the unaudited consolidated statement of operations for the three months ended March 31, 2005.

Previously, in March 2004, Novoste announced a reduction in force, eliminating 84 positions, to align Novoste's staffing with current market conditions. Fifty-nine of the employees involved in the reduction terminated employment with Novoste during the three months ended March 31, 2004.

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
Incurred and expensed	\$ 2,401	\$ 470
Paid and settled	(1,401)	(359)
Liability at end of period (included with accrued salaries)	\$ 1,000	\$ 111

**NOTE 16. RELATED PARTY TRANSACTIONS**

On December 23, 2002, the Company signed a Distribution Agreement with Orbus Medical Technologies, Inc., a manufacturer of cardiology products. The Company's President and Chief Executive Officer, Mr. Alfred J. Novak, was previously the Chairman of Orbus.

In February 2005, Novoste and Orbus mutually agreed to terminate the Distribution Agreement. Orbus paid Novoste \$346,000 and assumed \$36,000 in obligations to repurchase inventory, refund an unused deposit and reimburse Novoste for market development expenses. Novoste ceased distributing Orbus product by the end of the first quarter of 2005 and all inventory was returned.

Novoste had net sales of \$37,000 and \$135,000 from this product line in the quarters ending March 31, 2005 and 2004, respectively.



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**Report of Independent Registered Public Accounting Firm**

The Board of Directors

ONI Medical Systems, Inc.

We have audited the accompanying balance sheets of ONI Medical Systems, Inc. (the Company) as of December 31, 2004 and 2003 and the related statements of operations, redeemable convertible preferred stock and stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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 financial position of ONI Medical Systems, Inc. at December 31, 2004 and 2003 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that ONI Medical Systems, Inc. will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses and has generated negative cash flow from operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

As discussed in Note 2 to the financial statements, effective July 1, 2003, the Company adopted the provisions of Emerging Issues Task Force issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*.

/s/ ERNST & YOUNG LLP

April 13, 2005,

except for Note 12 as to which

the date is May 18, 2005

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**Table of Contents****ONI MEDICAL SYSTEMS, INC.****BALANCE SHEETS**

	March 31,		December 31,	
	2005	2005	2004	2003
	(Unaudited)	(Proforma) (Unaudited)		
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents	\$ 449,518	\$ 449,518	\$ 1,039,256	\$ 3,465,466
Restricted cash	50,000	50,000	50,000	
Accounts receivable, net of allowance for doubtful accounts of \$10,000, \$40,000 and \$40,000 at March 31, 2005, December 31, 2004 and 2003, respectively	1,223,491	1,223,491	2,451,100	814,969
Inventories	2,553,362	2,553,362	2,016,298	1,135,051
Rights under reseller agreement (Note 6)	416,000	416,000	421,000	
Prepaid expenses and other current assets	555,041	555,041	655,743	479,877
<b>Total current assets</b>	<b>5,247,412</b>	<b>5,247,412</b>	<b>6,633,397</b>	<b>5,895,363</b>
Property and equipment, net	489,363	489,363	523,551	970,286
Deposits	28,433	28,433	28,433	32,120
Rights under reseller agreement (Note 6)	522,778	522,778	624,778	
Other assets	775,726	775,726	18,831	7,801
<b>Total assets</b>	<b>\$ 7,063,712</b>	<b>\$ 7,063,712</b>	<b>\$ 7,828,990</b>	<b>\$ 6,905,570</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>				
Current liabilities:				
Accounts payable	\$ 2,514,920	\$ 2,514,920	\$ 1,925,844	\$ 1,043,549
Accrued expenses	1,896,561	1,896,561	1,700,179	1,108,522
Deferred revenue	1,353,798	1,353,798	1,724,890	528,818
Customer deposits	957,000	957,000	676,000	370,250
Obligations under reseller agreement (Note 6)	319,000	319,000	453,000	
<b>Total current liabilities</b>	<b>7,041,279</b>	<b>7,041,279</b>	<b>6,479,913</b>	<b>3,051,139</b>
Long-term liabilities				
Long-term deferred revenue	330,000	330,000		
Obligations under reseller agreement (Note 6)	330,000	330,000	397,000	
<b>Total liabilities</b>	<b>7,701,279</b>	<b>7,701,279</b>	<b>6,876,913</b>	<b>3,051,139</b>
Commitments and contingencies (Note 6)				
Redeemable convertible preferred stock:				
Preferred stock \$0.01 par value: 12,000,000, 12,000,000 and 11,500,000 shares authorized at March 31, 2005, December 31, 2004 and 2003, respectively; and 9,147,285, 9,147,285, 6,589,145 shares issued and outstanding at March 31, 2005, December 31, 2004 and 2003, respectively, at redemption value	11,800,000		11,800,000	8,500,000

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Stockholders' deficit:				
Common stock, \$0.01 par value: 22,500,000 shares authorized at March 31, 2005, December 31, 2004 and 2003; and 5,929,806, 5,929,806 and 5,929,815 shares issued and outstanding at March 31, 2005, December 31, 2004 and 2003, respectively				
	59,299	196,387	59,299	59,299
Additional paid-in capital	12,899,885	30,447,282	12,899,309	13,101,316
Accumulated deficit	(25,396,751)	(31,281,236)	(23,806,531)	(17,806,184)
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
Total stockholders' deficit	(12,437,567)	(637,567)	(10,847,923)	(4,645,569)
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 7,063,712	\$ 7,063,712	\$ 7,828,990	\$ 6,905,570
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>

See accompanying notes.

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**Table of Contents****ONI MEDICAL SYSTEMS, INC.****STATEMENTS OF OPERATIONS**

	<b>Three Months Ended March 31,</b>		<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>
	<b>(Unaudited)</b>				
<b>Revenue:</b>					
System revenue	\$ 2,255,830	\$ 572,455	\$ 8,303,236	\$ 8,245,133	\$ 6,276,217
Service revenue	216,418	82,993	583,719	52,203	
Other revenue	156,742				
<b>Total revenue</b>	<b>2,628,990</b>	<b>655,448</b>	<b>8,886,955</b>	<b>8,297,336</b>	<b>6,276,217</b>
<b>Cost of revenue:</b>					
Cost of system revenue	1,668,448	453,438	7,124,784	5,715,431	4,752,390
Cost of service revenue	300,276	304,455	701,608	45,721	
Cost of other revenue	156,742				
<b>Total cost of revenue</b>	<b>2,125,466</b>	<b>757,893</b>	<b>7,826,392</b>	<b>5,761,152</b>	<b>4,752,390</b>
<b>Gross profit (loss)</b>	<b>503,524</b>	<b>(102,445)</b>	<b>1,060,563</b>	<b>2,536,184</b>	<b>1,523,827</b>
<b>Operating expenses:</b>					
Research and development	602,449	466,151	1,843,178	1,782,525	2,328,161
Sales and marketing	976,995	963,079	3,392,418	2,291,395	1,893,762
General and administrative	514,088	443,478	1,821,788	1,313,863	1,255,100
<b>Total operating expenses</b>	<b>2,093,532</b>	<b>1,872,708</b>	<b>7,057,384</b>	<b>5,387,783</b>	<b>5,477,023</b>
<b>Loss from operations</b>	<b>(1,590,008)</b>	<b>(1,975,153)</b>	<b>(5,996,821)</b>	<b>(2,851,599)</b>	<b>(3,953,196)</b>
<b>Other income (expense):</b>					
Interest income	4,867	5,932	18,722	11,514	461
Interest expense	(9,356)	(1,548)			