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NEOPROBE CORP  
Form 10KSB  
March 30, 2004

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 10-KSB

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended: December 31, 2003

OR

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 0-26520  
NEOPROBE CORPORATION

-----  
(Name of Small Business Issuer in Its Charter)

DELAWARE

31-1080091

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(State or Other Jurisdiction of  
Incorporation or Organization)  
425 Metro Place North, Suite 300, Dublin, Ohio

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(I.R.S. Employer Identification  
No.)  
43017-1367

-----  
(Address of Principal Executive Offices)

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(Zip Code)

Issuer's telephone number, including area code: (614) 793-7500 Securities registered pursuant to Section 12(b) of the Act: None Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$.001 per share

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(Title of Class)

Rights to Purchase Series A Junior Participating Preferred Stock

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(Title of Class)

Check whether the Registrant: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B contained herein and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

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The issuer's revenues for the fiscal year ended December 31, 2003 were \$6,509,908.

The aggregate market value of shares of common stock held by non-affiliates of the registrant on March 15, 2004 was \$30,384,344.

The number of shares of common stock outstanding on March 15, 2004 was 53,881,696.

Transitional Small Business Disclosure Format (check one): Yes  No

### DOCUMENTS INCORPORATED BY REFERENCE

None.

## PART I

### ITEM 1. DESCRIPTION OF BUSINESS

#### DEVELOPMENT OF THE BUSINESS

We are a biomedical technology company providing innovative surgical and diagnostic products that enhance patient care by meeting the critical decision-making needs of healthcare professionals. We were originally incorporated in Ohio in 1983 and reincorporated in Delaware in 1988. Our executive offices are located at 425 Metro Place North, Suite 300, Dublin, Ohio 43017. Our telephone number is (614) 793-7500.

From our inception through the end of 2001, we devoted substantially all of our efforts and resources to the research and clinical development of innovative systems for the intraoperative diagnosis and treatment of cancers. Following an evaluation of our business plan during early 2001, however, we determined that we needed to expand our product portfolio and consider synergistic products outside the cancer or oncology fields.

In December 2001, we acquired Biosonix Ltd., a private Israeli company limited by shares. In February 2002, Biosonix Ltd. changed its name to Cardiosonix Ltd. (Cardiosonix). Cardiosonix is developing and commercializing a unique line of blood flow measurement devices for a variety of diagnostic and surgical applications. The decision to expand beyond our product focus on oncology was based on our belief that the Cardiosonix products would diversify our customer base through a product line we believe has great market potential and a path of market adoption similar to our gamma detection devices, but one that also has significant operational synergies in the development, regulation and manufacture to that of our existing gamma devices.

Although we have expanded our strategic focus to include blood flow medical devices, we intend to continue to execute many of the strategies outlined in prior years related to the internal development of gamma detection medical devices and to continue supporting development of our other complementary procedural-based technologies. Based upon information that we have recently become aware of, we are considering reactivating development activities concerning radioimmuguided surgery (RIGS(R)). In addition, we are preparing to begin the pivotal stage in the development of our proprietary lymphatic targeting agent, LYMPHOSEEK(TM).

Our business goals are to maximize the market potential of Cardiosonix' blood flow products as leaders in the measurement of blood flow in both clinical and surgical settings to supplement our leadership position in the current

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intraoperative gamma detection market. We believe our core device business lines will provide us with a strong operating foundation and enable us to judiciously evaluate and develop complementary procedural products with a recurring revenue stream. To that end, we intend to continue to pursue the development of LYMPHOSEEK and to evaluate potential development plan for RIGS.

### OUR TECHNOLOGY

#### Gamma Detection Devices

Through 2003, substantially all of our revenue has been generated from the sale of a line of gamma radiation detection devices and related products used by surgeons in the diagnosis and treatment of cancer and related diseases. Our currently-marketed line of gamma detection devices has been cleared by the FDA and other international regulatory agencies for marketing and commercial distribution throughout most major global commercial markets.

Our patented gamma detection devices consist of hand-held detector probes and a control unit. The detection device in the tip of the probe is a highly radiosensitive crystal that relays a signal through a preamplifier to the control unit to produce both a digital readout and an audible signal. The detector element fits into a housing approximately the size of a pocket flashlight. The NEO2000(R) Gamma Detection

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System, originally released in 1998, is the third generation of our gamma detection systems. The NEO2000 is designed as a platform for future growth of our instrument business. The neo2000 is software upgradeable and is designed to support future surgical targeting probes without the necessity of costly remanufacture. Since 1998, we have developed and released three major software upgrades for customer units designed to improve the utility of the system and/or offer the users additional features.

Surgeons are using our gamma detection devices in a surgical application referred to as sentinel lymph node biopsy (SLNB) or intraoperative lymphatic mapping (lymphatic mapping or ILM). ILM helps trace the lymphatic patterns in a cancer patient to evaluate potential tumor drainage and cancer spread in lymphatic tissue. The technique does not detect cancer; rather it helps surgeons identify the lymph node(s) to which a tumor is likely to drain and spread. The lymph node(s) (sometimes referred to as the "sentinel" node(s)) may provide critical information about the stage of a patient's disease. ILM begins when a patient is injected at the site of the main tumor with a commercially available radioactive tracing agent. The agent is intended to follow the same lymphatic flow as the cancer would if it had metastasized. The surgeon may then track the agent's path with a hand-held gamma-radiation-detection probe, thus following the potential avenues of metastases and identifying lymph nodes to be biopsied for evaluation and determination of cancer spread.

Numerous clinical studies, involving a total of nearly two thousand patients and published in peer-reviewed medical journals such as Oncology (January 1999) and The Journal of The American College of Surgeons (December 2000), have indicated ILM is approximately 97% accurate in predicting the presence or absence of disease spread in melanoma and breast cancers. Consequently, it is estimated that more than 80% of breast cancer patients who would otherwise have undergone full axillary lymph node dissections (ALND), involving the removal of as many as 20 - 30 lymph nodes, might be spared this radical surgical procedure if the sentinel node was found to be free of cancer. Surgeons practicing ILM have found that our gamma-detection probes are well suited to the procedure.

Lymphatic mapping has become the standard of care for treating patients with

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melanoma at many institutions. For breast cancer, the technique appears to be moving toward standard of care status at major cancer centers. Our marketing partner has seen continued growth in sales due partially to increased adoption of the ILM procedure and changes in the competitive landscape. Lymphatic mapping in breast cancer is the subject of national and international clinical trials, including studies sponsored by the U.S. Department of Defense, the NCI and the American College of Surgeons. Although we have been selling gamma detection devices for use in surgical oncology for over seven years, we believe many surgeons, both in the U.S. and the rest of the world have delayed adoption of lymphatic mapping pending the outcome of these important trials. We believe that once data from these trials are published; there will be an additional demand for our devices. We continue to monitor these trials and to work with our marketing partners and thought leaders in the surgical community to set up and support training courses internationally for lymphatic mapping. We also believe, based on anecdotal market intelligence, that over half of the potential global market for devices such as ours remains untapped. Courses showcasing our instruments continue to be held at many nationally and internationally renowned cancer-specializing and teaching institutions. These courses appear to be positively impacting the adoption of lymphatic mapping, albeit not as rapidly as we would like to see.

In addition to lymphatic mapping, surgeons are investigating the use of our device for other gamma guided surgery applications, such as evaluating the thyroid function, in determining the state of disease in patients with vulvar and penile cancers, and in SLNB in gastric and non-small cell lung cancers. Expanding the application of ILM beyond the current primary uses in the treatment of breast cancer and melanoma is the primary focus of our strategy regarding our gamma guided surgery products. To support that expansion, we continue to work with our marketing and distribution partners to develop software-based enhancements to the NEO2000 platform as well as probes such as the laparoscopic probe introduced in 2002 that supports the minimally invasive emphasis in today's practice of surgery. To that end, our primary goals for our gamma device business for 2004 center around working with our marketing partners to improve the market position of our laparoscopic approach and increase awareness of independent research being done to expand the application of ILM to other indications.

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### Blood Flow Measurement Devices

Accurate blood flow measurement is required for various clinical needs, including:

- real-time monitoring;
- intra-operative quantification;
- non-invasive diagnostics; and
- evaluation of cardiac function.

Currently, the medical community has no simple, immediate, real-time means to quantify the adequacy of organ perfusion, that is, the direct measurement of blood flow into the organ. Devices do exist that visually show perfusion of a target organ. We are unaware, however, of any device that provides an accurate, real-time measurement of blood flow in as many applications without having to isolate target vessels or conduct other invasive procedures.

In addition, blood flow velocity measurements are often confused with volume blood flow. These two variables, however, are normally different parameters that

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respond differently to pathological conditions and provide different data. Blood flow velocity is used primarily for determining the existence of a stenosis (narrowing or obstruction) in the vascular surgery setting, while the applications of blood flow volume have potential impact across a much broader range of medical disciplines.

Cardiosonix is developing and commercializing the QUANTIX(R) line of products that employ a unique and proprietary Angle-independent Doppler Blood Flow (ADBF(TM)) technology that allows for blood flow volume and velocity readings. Most current applications of Doppler technology to blood flow measurement are angle-dependent and therefore more prone to estimation errors and potential inaccuracy. ADBF eliminates calculation estimation and permits real-time measurement of volume blood flow.

The ADBF technology utilizes a special application of the Doppler method through simultaneous projection of a combination of narrow beams with a known angle between them. Thus, based on trigonometric and Doppler considerations, the angle of insonation can be obtained, resulting in accurate, angle-independent blood flow velocity measurements that do not require the use of complicated, expensive imaging systems. In order to obtain high-resolution velocity profiles, the QUANTIX devices use a multi-gated pulse wave Doppler beam. With this method, specific sample volumes along the ultrasound beam can be separately evaluated, and the application of a flow/no flow criterion can be made. The Cardiosonix technology applies a special use of digital Doppler technology, which with the digital signal processing power of the system allows hundreds of sample volumes to be sampled and processed simultaneously, thus providing high resolution velocity profiles for both angle and vascular diameter calculations, and subsequently volume blood flow measurements. At present, Cardiosonix has two products in the early stages of commercialization and one still in development that are designed to provide blood flow measurement and cardiac output information to physicians in cardiac/vascular surgery, neurosurgery and critical care settings.

QUANTIX/ND(TM) is designed to allow neurosurgeons and neurologists, as well as intensive care unit or emergency room physicians, to non-invasively measure carotid artery blood flow in a simple and real-time manner. QUANTIX/ND consists of a control unit and an angle-independent ultrasound probe that obtains signals directly from the carotid artery in a non-invasive manner. QUANTIX/ND is designed primarily for use in monitoring head trauma patients in neuro-intensive care units and emergency rooms. Periodic blood flow measurements minimize the risk of brain impairment. We are unaware of any measurement system on the market today that provides real-time, bedside, non-invasive, continuous, direct and accurate measurements of complete hemodynamic parameters including blood flow. Other modalities that do monitor capabilities of the brain are significantly more invasive, expose the patient to incremental risk or are inherently complicated, offering only indirect estimation of perfusion conditions. Some medical devices use an estimated measurement of blood flow velocity to create an index of blood flow but do not account for instantaneous changes in vascular cross-sectional area. In most competing devices, however, blood flow velocity is angle-dependent and cannot be measured accurately. The QUANTIX/ND device, as well as its predecessor device, the FLOWGUARD(TM), has received CE mark regulatory clearance

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for marketing in the European Union (EU) as well as FDA 510(k) clearance for marketing in the United States.

QUANTIX/OR(TM) is designed to permit cardiovascular surgeons and assisting physicians to obtain intraoperative volume blood flow readings in various targeted blood vessels within seconds. The system consists of an

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angle-independent ultrasound probe and digital numerical displays of blood flow rate. Thus, the surgeon obtains immediate, real-time and quantitative readings while focused on the target vessel. Quantifying blood flow is crucial during anastomotic or other bypass graft procedures to determine adequate blood flow. While measurement is advisable whenever a blood vessel is exposed intra-operatively, generally this is not the current practice.

Ultimately, in practice, the surgeon generally resorts to using his eyes and fingers in a process called finger palpation to qualitatively assess vessel flow. The QUANTIX/OR offers the surgeon immediate and simple quantitative assessment of blood flow in multiple blood vessels and grafts. The primary advantage of finger palpation is that it is fast and simple; the disadvantages are that it requires a good deal of experience, it is difficult to perform in vessels embedded in tissue, it can become difficult to interpret in large vessels, and it permits only a very qualitative and subjective assessment. A significant partial occlusion (or even a total occlusion) will result in significant vessel "inflation" and strong palpations that could mislead the surgeon. Instead of such a subjective clinical practice that is highly experience-dependent, the QUANTIX/OR is designed to allow the surgeon to rely on more evidence-based medicine.

We believe that QUANTIX/OR represents a significant improvement over existing technologies to directly measure blood flow intraoperatively. Other technologies that attempt to measure intraoperative blood flow directly are generally more invasive and are impractical when multiple vessel measurements are required. They are, therefore, not used routinely in the operating room, so surgeons most often resort to finger palpation to qualitatively, rather than quantitatively, measure vessel perfusion. The QUANTIX/OR device has received CE mark regulatory clearance for marketing in the EU and FDA 510(k) clearance for marketing in the United States.

QUANTIX/TE(TM) is being designed as a transesophageal cardiac function monitor for measuring blood flow in the descending aorta in critical care settings. The system employs a special transesophageal catheter for quantitative assessment of blood flow in the descending aorta for cardiac output calculations. The system is designed for bedside use in intensive care settings. Cardiac output and function monitoring is essential in critical care and trauma patients. The procedure of transesophageal monitoring is a well-recognized clinical modality, particularly for echocardiography of the heart. Only highly invasive methods of cardiac output via thermodilution techniques are currently available, or indirect and non-invasive methods such as bioimpedance with an unknown degree of clinical significance. The QUANTIX/TE is still in the early stages of development and is not currently cleared for commercial sale in any market.

Our strategy related to Cardiosonix products for 2004 continues to emphasize the three primary objectives we established in 2003:

- to promote and expand the clinical evaluation of the QUANTIX/ND and QUANTIX/OR with thought leaders in the neurosurgical and cardiac arenas;
- to secure and train additional marketing and distribution partners for key global markets for the QUANTIX/ND and QUANTIX/OR devices; and
- to achieve commercial sales of Cardiosonix' Quantix products beyond demonstration unit sales that would demonstrate the initial market acceptance of the products.

We cannot assure you, however, that any of Cardiosonix' products will achieve market acceptance. See also Risk Factors.

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### Lymphoseek

Our gamma detection devices are primarily capital in nature; as such, they generate revenue only on the initial sale. To complement the one-time revenue stream related to capital products, we are working on

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developing recurring revenue or "procedural" products that would generate revenue based on each procedure in which they were used. Our primary efforts in this area involve an exclusive worldwide license agreement with the University of California, San Diego (UCSD) for a proprietary compound we refer to as LYMPHOSEEK. We believe LYMPHOSEEK, if proven effective, could be used as a lymph node locating agent in ILM procedures. Neoprobe and UCSD completed pre-clinical evaluations of LYMPHOSEEK in 2001 and completed a Phase I trial in the treatment of breast cancer in humans. The initial Phase I studies of LYMPHOSEEK in breast cancer were funded through a research grant from the Susan G. Komen Breast Cancer Research Foundation. Preliminary results from the Phase I breast trial were presented at the Spring 2002 meeting of the Society of Nuclear Medicine.

A Phase I/II clinical trial in melanoma patients was completed during the third quarter of 2003. The Phase I/II melanoma trial was funded through a research grant from the American College of Surgeons. Our discussions held to date with potential strategic partners to assist in the further development and commercialization of LYMPHOSEEK have focused on gaining a better understanding of the regulatory approval process related to LYMPHOSEEK. To that end, we held a meeting in November 2003 with the Interagency Council on Biomedical Imaging in Oncology (Interagency Council), an organization representing the FDA, the NCI and the Centers for Medicare and Medicaid Services to discuss the regulatory approval process and to determine the objectives for the next clinical trial involving LYMPHOSEEK. As a result of that meeting, we are preparing for the submission of a clinical protocol to the FDA for a pivotal trial to support the marketing approval of LYMPHOSEEK. We expect to submit the protocol to the FDA before the end of the third quarter of 2004. We cannot assure you, however, that this product will achieve regulatory approval, or if approved, that it will achieve market acceptance. See also Risk Factors.

### RIGS

From inception until 1998, Neoprobe devoted significant efforts and resources to the development of its proprietary RIGS technology. The RIGS system combines a patented hand-held gamma radiation detection probe, proprietary radiolabeled cancer targeting agents, and patented surgical methods to provide surgeons with real-time information to locate tumor deposits not detectable by conventional methods, and to assist in more thorough removal of the cancer. The RIGS system is designed to assist the surgeon in the more thorough removal of the cancer, thereby leading to improved surgical treatment of the patient. The targeting agents used in the RIGS process are monoclonal antibodies, labeled with a radioactive isotope that emits low energy gamma rays. The device used is a very sensitive radiation detection instrument that is capable of detecting small amounts of radiation bound to the targeting agent. Before surgery, a cancer patient is injected with one of the targeting agents which circulates throughout the patient's body and binds specifically to cancer cell antigens or receptors. Concentrations of the targeting agent are then located during surgery by Neoprobe's gamma-detection device, which emits an audible tone to direct the surgeon to targeted tissue.

RIGSCAN CR49 is an intraoperative radiodiagnostic agent consisting of a radiolabeled murine monoclonal antibody (Mab CC49). The radiolabel used is <sup>125</sup>I, a 27 - 35 KeV emitting isotope. The MAb used in RIGSCAN CR49 is the CC49 MAb developed by the NCI and licensed to Neoprobe by the NIH. The CC49 MAb is

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produced from a murine cell line generated by the fusion of splenic lymphocytes from mice immunized with tumor-associated glycoprotein-72 (TAG-72) with non-immunoglobulin secreting P3-NS-1-Ag4 myeloma cells. The CC49 MAb localizes or binds to TAG-72 and shows a strong reactivity with both LS-174T colon cancer extract and to a breast cancer extract.

RIGSCAN CR49 is the biologic component for the RIGS system to be used in patients with colon or rectal cancer. The RIGS system is designed to be a diagnostic aid in the intraoperative detection of clinically occult disease. RIGSCAN CR49 is intended to be used in conjunction with other diagnostic methods, for the detection of the extent and location of tumor in patients with colorectal cancer. The detection of clinically occult tumor provides the surgeon with a more accurate assessment of the extent of disease and, therefore, may impact the surgical and therapeutic management of the patient. Clinical trials suggest that RIGSCAN CR49 provides additional information outside that provided by standard diagnostic modalities (including surgical exploration) that may aid in patient management. Specifically, RIGSCAN

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CR49 used as a component of the RIGS system confirms the location of surgically suspicious metastases, evaluates the margins of surgical resection, and detects occult tumor in perihepatic (portal and celiac axis) lymph nodes.

Neoprobe conducted two Phase III studies, NEO2-14 and NEO2-13, of RIGSCAN CR49 in patients with colorectal cancer. Both studies were multi-institutional involving cancer treatment institutions in the United States, Israel, and Europe. The primary endpoint of both studies was to demonstrate that RIGSCAN CR49 detected pathology-confirmed disease that had been undetected by traditional preoperative (i.e., CT Scans) or intraoperative (i.e., surgeon's visual observations and palpation) means. That is, the trials were intended to show that the use of RIGSCAN CR49 assisted the surgeon in the detection of occult tumor. In December 1996, Neoprobe submitted applications to the European Agency for the Evaluation of Medicinal Products (EMEA) and the FDA for marketing approval of RIGSCAN CR49 for the detection of metastatic colorectal cancer.

Clinical study NEO2-14, which was submitted to the FDA in the RIGSCAN CR49 Biologic License Application (BLA), enrolled 151 colorectal cancer patients with either suspected metastatic primary colorectal disease or recurrent colorectal disease. During the FDA's review of the BLA, 109 of the enrolled patients were determined to be evaluable patients. Clinical study NEO2-13 was conducted in 287 enrolled patients with primary colorectal disease. The primary end-point for clinical study NEO2-13 was the identification of occult tumor.

NEO2-14 was the pivotal study submitted with Neoprobe's referenced BLA. Two additional studies evaluating patients with either primary or metastatic colorectal disease, NEO2-11 (a multi-center study) and NEO2-18 (a single institution study), were included in the BLA and provided supportive proof of concept (i.e., localization and occult tumor detection) and safety data. A study report for NEO2-13 was not submitted under the BLA and the FDA undertook no formal review of the study.

Following review of its applications, we received requests for further information from the FDA and from the European Committee for Proprietary Medicinal Products (CPMP) on behalf of the EMEA. Both the FDA and EMEA acknowledged that our studies met the diagnostic endpoint of the Phase III clinical study, which was to provide incremental information to the surgeon regarding the location of hidden tumor. However, both agencies wanted to know how the finding of additional tumor provided clinical benefit that altered patient management or outcome. In a series of conversations with the FDA the product claims were narrowed to the intraoperative detection of hepatic and



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perihepatic disease in patients with advanced colorectal cancer and patients with recurrent colorectal cancer.

The FDA determined during its review of the BLA review that the clinical studies of RIGSCAN CR49 needed to demonstrate clinical utility in addition to identifying additional pathology confirmed disease. In discussions between Neoprobe and the agency, an FDA driven post hoc analysis plan was developed to limit the evaluation of RIGSCAN CR49 to patients with hepatic and perihepatic disease with known metastasis to the liver. Findings of "occult" disease and subsequent changes in patient management (i.e., abandoning otherwise risky hepatic resections) in this limited population would serve as a measure of patient benefit. The FDA's analysis of the patients enrolled in NEO2-14 matching the limited criteria was evaluated with a determination to confirm the surgical resection abandonment outcome. The number of evaluable patients in this redefined patient population was deemed too small by the agency and the lack of pre-stated protocol guidance precluded consistent sets of management changes given similar occult findings. The number of evaluable patients for any measure of clinical utility, therefore, was too small to meet relevant licensing requirements and the FDA ultimately issued a not approvable letter for the BLA on December 22, 1997, describing certain clinical and manufacturing deficiencies. Neoprobe also withdrew its application to the EMEA in November 1997.

We developed a clinical response plan for both agencies during the first half of 1998. However, following our analysis of the regulatory pathways for approval that existed at that time, we determined that we did not have sufficient financial resources to conduct the additional studies requested and sought to identify others with an interest in continuing the development process.

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Over the last several years, we have held preliminary discussions with several parties potentially interested in continuing the RIGS development; however, only one of those discussions resulted in an arrangement that attempted to restart the development of RIGS. During 2000, we executed and amended an agreement with OncoSurg Ltd. (OncoSurg, formerly NuRIGS Ltd.), that provided OncoSurg with an option exercisable through December 31, 2001 to license the RIGS technology for use in the diagnosis and treatment of colorectal cancer. During 2001, OncoSurg conducted pre-clinical testing and sponsored a Phase I physician's Investigational New Device (IND) clinical trial for colorectal cancer using a second-generation humanized version of our RIGSCAN CR49 antibody. However, OncoSurg did not exercise its option to continue development at the end of 2001 due to a lack of funding which we believe is unrelated to the pending clinical results of the current Phase I trial. The physician-IND researchers reported favorable results of the Phase I trial during fourth quarter of 2003.

We recently obtained results of a third party's survival analysis suggesting that RIGSCAN CR49 may be predictive of, or actually contribute to, a positive outcome when measuring survival of the patients that participated in our original BLA studies. The data or its possible significance was unknown at the time of the BLA review given the limited maturity of the follow-up experience. The data includes publication by some of the primary investigators involved in the Phase III RIGS trials who have independently conducted survival follow-up analyses to their own institution's RIGS trial patients with apparently favorable results relating to the long-term survival prognosis of patients who were treated with RIGS. In addition, we have recently learned that the FDA has held the BLA originally filed with the FDA in 1996 open. Based primarily on these pieces of information, we requested, and have been granted, a meeting with the FDA to discuss the possible next steps for evaluating the survival related to our previous Phase III clinical trials as well as the possible submission of this data, if acceptable, as a prospective analysis in response to questions

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originally asked by the FDA in response to our original BLA. Our meeting with the FDA has been scheduled for April 15, 2004.

If our plan for evaluating the survival data is received positively, we intend to engage the services of a clinical research organization (CRO) to review these survival findings related to all evaluable patients from our Phase III primary and metastatic colorectal cancer clinical trials. The analysis of this data may answer some of the questions raised by the FDA in response to our original application; however, the RIGSCAN CR49 drug has not been produced for several years and we believe it is likely we would have to perform some additional work related to ensuring the drug cell line is still viable and submit this data to the FDA for their evaluation before approval could be considered. Neoprobe is in the process of initiating discussions with established biologic manufacturing organizations to determine the costs and timelines associated with the production of commercial quantities of the CC49 antibody. In addition, we will need to establish a process for radiolabeling the CC49 antibody in order to meet the regulatory needs for the RIGSCAN CR49 product. At this time, we have not examined the possible steps towards a similar re-invigoration of the process for approval with the EMEA. We intend to re-evaluate that situation once the approval process with the FDA has been clarified.

We are encouraged by the recent developments regarding RIGS and believe that a positive outcome from our upcoming meeting with the FDA could represent a dramatic turnaround in the development for RIGS. We believe we would need to obtain additional funding and/or identify a development partner in order to carry out all the activities necessary for commercialization. We do not have any agreements in place or pending with third parties that would ensure the continued development of the RIGS process beyond the FDA meeting scheduled for April 15th and the completion of the survival analysis being proposed to the FDA at the April 15th meeting. In addition, even if we are able to make such arrangements on satisfactory terms, we believe that the time required for continued development, regulatory approval and commercialization of a RIGS product would likely be a minimum of two years before we receive any significant product-related royalties or revenues. However, we cannot assure you that we will be able to complete definitive agreements with a development partner for the RIGS technology and does not know if a partner will be obtained on a timely basis on terms acceptable to us, or at all. We cannot assure you that the FDA or the EMEA will approve our RIGS products for marketing, or that any such products will be successfully introduced or achieve market acceptance. See Risk Factors.

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### Activated Cellular Therapy

We have performed early stage research on another technology platform, activated cellular therapy (ACT), based on work originally done in conjunction with the RIGS technology. ACT is intended to boost the patient's own immune system by removing lymph nodes identified during surgery and then, in a cell processing technique, activating and expanding "helper" T-cells found in the nodes. Within 10 to 14 days, the patient's own immune cells, activated and numbering more than 20 billion, are infused into the patient in an attempt to trigger a more effective immune response to the cancer.

During the second quarter of 2001, we announced a research collaboration with Aastrom Biosciences, Inc. (Aastrom) intended to determine whether Aastrom's Replicell(TM) system would be able to duplicate cell expansion results experienced in previous Phase I clinical testing of our ACT technology for oncology. Unfortunately, we experienced delays in completing the evaluation in 2001 due to a lack of available tissue for testing purposes and since that time have not had the funding available to move the research forward. From time to

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time, we have engaged investment banking firms as we did for the RIGS technology to assist us in identifying parties to license or purchase the ACT technology. However, these efforts have not resulted in the identification of a development partner, purchaser or licensee to date. We do not know if a partner will be identified on a timely basis, on terms acceptable to us, or at all. Although the prospects for ACT may be improved depending on the outcome of a decision to renew development efforts for RIGS, we currently do not intend to fund any significant ACT-related research and development without a partner. We cannot assure you that any ACT products will be successfully developed, tested or licensed, or that any such products will gain market acceptance. See also Risk Factors.

### MARKET OVERVIEWS

The medical device marketplace is a fast growing market. Medical Device & Diagnostic Industry magazine reports an annual medical device and diagnostic market of \$75 billion in the U.S. and \$169 billion internationally.

#### Cancer Market Overview

Cancer is the second leading cause of death in the U.S. and Western Europe and is responsible for over half a million deaths annually in the U.S. alone. The NIH estimates the overall annual costs for cancer (the primary focus of our products) for the U.S. in the year 2003 at \$189.5 billion: \$64.2 billion for direct medical costs, \$16.3 billion for indirect morbidity, and \$109 billion for indirect mortality. Our line of gamma detection systems is currently used primarily in the application of ILM in breast cancer and melanoma which, according the American Cancer Society (ACS), are expected to account for 16% and 4%, respectively, of new cancer cases in the U.S. in 2004.

NIH has estimated that breast cancer will annually affect approximately 500,000 women in North America, Western Europe, and other major economic markets. Breast cancer is the leading cause of death from cancer in the United States among the 30 million women between the ages of 40 and 55 and the second leading cause of death from cancer among all women. According to the ACS, over 200,000 new cases of invasive breast cancer are expected to be diagnosed and over 40,000 women are expected to die from the disease during 2004 in the U.S. alone. The incidence of breast cancer increases with age, rising from about 100 cases per 100,000 women at age 40 to about 400 cases per 100,000 women at age 65. Thus, we believe that the significant aging of the population, combined with improved education and awareness of breast cancer and diagnostic methods, will lead to an increased number of breast cancer surgical diagnostic procedures.

Approximately 80% of the patients diagnosed with breast cancer undergo a lymph node dissection (either ALND or SLNB) to determine if the disease has spread. While many breast cancer patients are treated in large cancer centers or university hospitals, regional and/or community hospitals currently treat the majority of breast cancer patients. Over 10,000 hospitals are located in the markets targeted for our gamma detection ILM products. While we are aware of no published statistics on the number of institutions that currently are using gamma detection devices in ILM, we believe that approximately fifty

percent of the total potential global market for gamma detecting devices remains to be penetrated at this time. However, if the potential of LYMPHOSEEK as a radioactive tracing agent is ultimately realized, it has the potential to address not only the current breast and melanoma markets on a procedural basis, but to also assist in the clinical evaluation and staging of solid tumor cancers and expanding ILM to additional indications, such as gastric, non-small cell lung and other solid tumor cancers.

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We estimate the total market potential for LYMPHOSEEK, if ultimately approved for all of these indications, could exceed \$200 million. However, we cannot assure you that LYMPHOSEEK will be approved, or if approved, that it will achieve the prices or sales we have estimated.

The ACS estimates that over 174,000 new incidences of colorectal and related cancers will occur in the U.S. in 2004. Based on an assumed recurrence rate of 40%, this would translate into total potential surgical procedures of over 240,000 annually in the U.S. alone. We believe the number of procedures in other markets of the world to be approximately two times the estimated U.S. market. As a result, we believe the total potential global market for RIGSCAN CR49 could, depending on the reimbursement allowed for RIGSCAN CR49, be in excess of \$1 billion annually. However, we cannot assure you that RIGSCAN CR49 will be approved, or if approved, that it will receive the reimbursement or achieve the level of sales we have currently estimated.

### Blood Flow Market Overview

Cardiovascular disease is the number one killer of men and women in the U.S. and in a majority of countries in the rest of the world that track such statistics. In the U.S. alone, the Centers for Disease Control (CDC) estimated that there were over 65 million physician office visits and over 6.8 million outpatient department visits in 2000 with a primary diagnosis of cardiovascular disease. The CDC registered over 5.9 million inpatient cardiovascular procedures in the U.S. during 2000 that directly involve cardiovascular circulation. We, as well as our competitors and other industry analysts, generally estimate the rest of the world's incidence of such modalities at roughly twice U.S. estimates.

The American Heart Association (AHA) estimates the total cost of cardiovascular diseases and stroke in the United States will exceed \$368.4 billion in 2004. A substantial portion of these expenditures is expected to be for non-invasive image and intravascular examination. In 1999, these modalities, employed in approximately 99 million diagnostic procedures, generated more than \$2.4 billion worldwide in product sales. Industry analysts have also estimated the worldwide market for multi-functional patient monitoring equipment totaled \$6.6 billion in 1999.

We have identified three distinct markets within the hospital setting for Cardiosonix' products:

- non-invasive diagnostics (QUANTIX/ND);
- intraoperative assessment (QUANTIX/OR); and
- critical care monitoring (QUANTIX/TE).

The American Hospital Association has estimated there are approximately 6,000 hospitals in the U.S., over half of which house one hundred beds or more (i.e., large hospitals). The American Association of Operating Room Nurses has estimated there are approximately 30,000 operating rooms in the U.S. Based on these estimates, information obtained from industry sources and data published by our competitors and other medical device companies, we estimate the worldwide totals for hospitals and operating rooms to be approximately two to two-and-a-half times the U.S. totals. In addition, the NCHS estimates that 516,000 cardiac bypass grafts were performed in the U.S. in 2001 on 305,000 patients.

Based on the above number of institutions and procedures, assuming the larger hospitals could use two or more systems of each type to support their activities, and assuming we are able to achieve market prices that are comparable to what our competitors are achieving (estimated at averaging \$25,000

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to \$30,000 per system or up to \$180 per procedural use), we believe the worldwide market potential for blood flow measurement products, such as those being developed by Cardiosonix, to be more than \$1.5 billion. We believe that gaining even a modest share of this market would result in significant annual revenues for our company. We cannot assure you, however, that Cardiosonix products will achieve market acceptance and generate the level of sales or prices anticipated.

### MARKETING AND DISTRIBUTION

#### Gamma Detection Devices

We began marketing the current generation of our gamma detection systems, the NEO2000, in October 1998. Since October of 1999, our gamma detection systems have been marketed and distributed throughout most of the world through Ethicon Endo-Surgery, Inc. (EES), a Johnson and Johnson company. In Japan, however, we market our products through a pre-existing relationship with Century Medical, Inc. (CMI).

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The heart of the NEO2000 system is a control unit that is software-upgradeable, permitting product enhancements without costly remanufacturing. Since the original launch of the NEO2000 system, we have introduced an enhanced version of our 14mm reusable probe optimized for lymphatic mapping procedures and a laparoscopic probe intended for certain minimally invasive procedures. We have also developed three major software version upgrades for the system that have been made available for sale to customers. We intend to continue developing additional ILM-related probes and instrument products in cooperation with EES to maintain our leadership position in the ILM field.

Physician training is critical to the use and adoption of ILM products by surgeons and other medical professionals. Our company and our marketing partners have established relationships with leaders in the ILM surgical community and have established and supported training courses internationally for lymphatic mapping. We intend to continue to work with our partners to expand the number of ILM training courses available to surgeons.

We entered into our current distribution agreement with EES effective October 1, 1999 for an initial five-year term with options to extend for two successive two-year terms. EES recently notified us of their desire to exercise their option for the first of the two-year term extensions, thus extending the term of our current agreement through December 31, 2006. Under this agreement, we manufacture and sell our ILM products almost exclusively to EES, who distributes the products globally (except for Japan). EES agreed to purchase minimum quantities of our products over the first three years of the five-year original term of the agreement and to reimburse us for certain research and development costs during the first three years and a portion of our warranty costs. EES' minimum purchase and reimbursement commitments were satisfied during 2002. EES has no ongoing purchase or reimbursement commitments to us other than the rolling four-month binding purchase commitment for gamma detection devices as outlined in the distribution agreement. Our agreement with EES also contains certain termination provisions and licenses to our intellectual property that take effect only in the event we fail to supply product, or for other reasons such as a change of control. See also Risk Factors.

#### Gamma Detection Radiopharmaceuticals

Due to the recency of the reinvigoration of our development efforts related to RIGSCAN CR49, we have not established a marketing or distribution channel for this product. We anticipate initiating such discussions following the

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establishment of a development timeline following our April 15, 2004 meeting with the FDA. We have had initial discussions with parties who may be interested in marketing and distribution of LYMPHOSEEK; however, such discussions to date have been preliminary in nature and have not resulted in any definitive arrangements at this time. We cannot assure you that we will be able to secure marketing and distribution partners for RIGS or LYMPHOSEEK, or if secured, that such arrangements will result in significant sales of either product.

### Blood Flow Measurement Devices

During late 2002, we received regulatory clearance to market QUANTIX/ND in the U.S. and the EU and placed a small number of devices with two distributors covering three countries for their demonstration purposes. Since the end of 2002, we have received CE Mark clearance to market the QUANTIX/OR in the EU and 510(k) clearance to market the device in the U.S. Currently, we have five distributors covering seven countries for the QUANTIX/ND and nine distributors covering over fifteen countries for the QUANTIX/OR. We are in active dialogue for marketing and distribution rights with a number of parties, primarily independent distributors which have territory or country-specific sales forces. The majority of the distributors signed to date are in the EU, South America and the Pacific Rim. In the United States, we are engaging independent cardiovascular sales organizations to sell and promote the use of the QUANTIX/OR. We have agreements completed or pending for a majority of states in the U.S.

We anticipate spending a significant amount of time and effort in 2004 to penetrate the end-user market. We will need to complete the training of our distributors and independent sales agents and work through them with thought leaders in the cardiac and neurosurgical fields to gain penetration at the end-user level. We anticipate placing some additional blood flow systems with industry thought leaders to obtain critical

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pre-commercialization feedback; however, we plan to continue working with the thought leaders already identified to promote publication in support of more widespread market launch. To date, we have placed a small number of devices with thought leaders in the U.S. and EU to support clinical investigations by their institutions. We are also investigating different sales models that include both capital sales and per use or lease-type transactions. We expect the sales model will evolve over the initial months of sales. The market education process we envision will likely take some time to develop in the manner we desire. In addition, the sales cycle for capital medical devices such as our blood flow products is typically a four to six month cycle. As such, significant end customer sales, if they occur, will likely lag the signing of distribution arrangements.

### MANUFACTURING

#### Gamma Detection Devices

We rely on independent contract manufacturers, some of which are single-source suppliers, for the manufacture of the principal components of our current line of gamma detection system products. See also Risk Factors. The NEO2000 system is comprised of a software-upgradeable NEO2000 control unit, a hand-held gamma detection probe and some accessories. We currently market a 14mm reusable probe and a laparoscopic reusable probe.

We have devoted significant resources to develop production capability for our gamma detection systems at qualified contract manufacturers. Production of the NEO2000 control unit, the 14mm probe and the laparoscopic probe involve the

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manufacture of components by a combination of subcontractors, including but not limited to eV Products, a division of II-VI Corporation (eV), and TriVirix International, Inc. (TriVirix). Currently, we have manufacturing and supply agreements with eV for the production of crystal modules used in the detector probes and for the manufacture of the 14mm probe and the NEO2000 control unit at TriVirix. We also purchase certain accessories for our line of gamma detection systems from other qualified manufacturers.

In December 1997, we entered into a supply agreement with eV for the supply of certain crystals and associated electronics to be used in the manufacture of our proprietary line of hand-held gamma detection probes. The original term of the agreement expired on December 31, 2002, but was automatically extended through December 31, 2005; however, the agreement is no longer exclusive for the last three years. eV supplies 100% of the crystals used in our products. While eV is not the only potential supplier of such crystals, any prolonged interruption of this source could restrict the availability of our probe products, which would adversely affect our operating results.

In October 2001, we entered into a manufacturing and supply agreement with UMM Electronics, Inc. (UMM) for the exclusive manufacture of our 14mm probe and NEO2000 control unit. The original term of the agreement was to expire in February 2005; however, we terminated our relationship with UMM during the fourth quarter of 2003. In the process of evaluating contract manufacturers for the QUANTIX product line, we had identified a different contract manufacturer, TriVirix, and concluded that it would be financially and operationally beneficial to us to have the NEO2000 and 14mm probe manufactured at the same location as the QUANTIX products.

In February 2004, we executed a Product Supply Agreement with TriVirix for the manufacture of the NEO2000 and 14mm probe. We have now completed the transfer of the manufacturing for the NEO2000 and 14mm probes to TriVirix. TriVirix began providing 14mm probes during February and the NEO2000 control unit during March 2004 for shipment to EES

We cannot assure you that we will be able to maintain agreements with our subcontractors on terms acceptable to us, or that our subcontractors will be able to meet our production requirements on a timely basis, at the required levels of performance and quality. In the event that any of our subcontractors is unable or unwilling to meet our production requirements, we cannot assure you that an alternate source of supply could be established without significant interruption in product supply or without significant adverse impact to product availability or cost. Any significant supply interruption or yield problems that we or our

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subcontractors experience would have a material adverse effect on our ability to manufacture our products and, therefore, a material adverse effect on our business, financial condition, and results of operations until a new source of supply is qualified. See also Risk Factors.

### Gamma Detection Radiopharmaceuticals

Due to the recency of the reinvigoration of our development efforts related to RIGSCAN CR49, we have not established a marketing or distribution channel for this product. We will need to establish biologic production and radiolabeling capabilities for the RIGS product before RIGSCAN CR49 can be commercialized. We have held initial discussions with parties who may assist in the manufacturing validation of the RIGSCAN product; however, these discussions have been preliminary in nature and we cannot assure you that the parties we have contacted will ultimately participate in the manufacture of RIGSCAN CR49. We

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anticipate continuing such discussions following the establishment of a development timeline following our April 15, 2004 meeting with the FDA. We have had initial discussions with parties who may be interested in producing LYMPHOSEEK; however, such discussions to date have been preliminary in nature and have been primarily related to manufacturing validation efforts. We cannot assure you that we will be successful in securing the necessary biologic product and/or radiolabeling capabilities.

### Blood Flow Measurement Devices

Currently, the QUANTIX products being distributed are being manufactured at Cardiosonix' facility in Israel. However, consistent with our stated objectives, we evaluated different contract manufacturers for the control unit portion of the QUANTIX product line during the first quarter of 2003 and solicited competitive bids. During the second quarter of 2003, we selected TriVirix to assemble the control unit portion of the QUANTIX line. In February 2004, we executed a Product Supply Agreement for the assembly of the blood flow control units with TriVirix; however, we are working with TriVirix to maintain some level of component sourcing from Israel that will satisfy our royalty requirements to the Israeli government (See Risk Factors).. Assembly of the QUANTIX control units at TriVirix is expected to start during the second half of 2004. The ultrasound probes distributed with the QUANTIX control units, while assembled at Cardiosonix' facility, use ultrasound transducers manufactured by Vermon S.A. (Vermon) of France. We currently purchase the ultrasound transducer modules from Vermon under purchase orders. We are in the process of evaluating subcontractors to manufacture the ultrasound probes and other accessories associated with the QUANTIX product line.

We cannot assure you that we will be able to finalize supply and service agreements with Vermon or other subcontractors for the QUANTIX products, that we will be able to maintain our agreement with TriVirix, or that our subcontractors will be able to meet our production requirements on a timely basis, at the required levels of performance and quality. In the event that any of our subcontractors is unable or unwilling to meet our production requirements, we cannot assure you that an alternate source of supply could be established without significant interruption in product supply or without significant adverse impact to product availability or cost. Any significant supply interruption or yield problems that we or our subcontractors experience would have a material adverse effect on our ability to manufacture our products and, therefore, a material adverse effect on our business, financial condition, and results of operations until a new source of supply is qualified. See also Risk Factors.

In addition, we determined that development of the QUANTIX line had progressed to the point where we did not need the number of development staff we had in order to support the final development phases and to support our commercialization efforts. As such, we reduced employment at our Cardiosonix subsidiary during the fourth quarter of 2003. We have entered into new employment arrangements with certain key personnel in Israel in order to continue to provide limited developmental and commercial support for the QUANTIX products.

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### COMPETITION

We face competition from medical product and biotechnology companies, as well as from universities and other non-profit research organizations in the field of cancer diagnostics and treatment. Many emerging medical product companies have corporate partnership arrangements with large, established companies to support the research, development, and commercialization of products that may be



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competitive with our products. In addition, a number of large established companies are developing proprietary technologies or have enhanced their capabilities by entering into arrangements with or acquiring companies with technologies applicable to the detection or treatment of cancer and the measurement of blood flow. Many of our existing or potential competitors have substantially greater financial, research and development, regulatory, marketing, and production resources than we have. Other companies may develop and introduce products and processes competitive with or superior to those of ours. See also Risk Factors.

For our products, an important factor in competition is the timing of market introduction of our products or those of our competitors' products. Accordingly, the relative speed with which we can develop products, complete the regulatory clearance processes and supply commercial quantities of the products to the market is an important competitive factor. We expect that competition among products cleared for marketing will be based on, among other things, product efficacy, safety, reliability, availability, price, and patent position.

### Gamma Detection Devices

With the emergence of ILM, a number of companies have begun to market gamma radiation detection instruments. Most of the competitive products have been designed from an industrial or nuclear medicine perspective rather than being developed initially for surgical use. Through 2002, the principal competitive product in both the United States and Europe was a gamma detection system marketed by US Surgical Corporation, a subsidiary of Tyco International Ltd.; however, we believe, based on competitive intelligence, that US Surgical has retreated from the sale of gamma detection devices in the U.S. and certain other global markets. We also compete with products produced by Care Wise Medical Products Corporation, PI Medical Diagnostic Equipment B.V., Pol.Hi.Tech. Srl, Silicon Instruments GmbH and other companies.

It is often difficult to glean accurate competitive information within the lymphatic mapping field, primarily because most of our competitors are either subsidiaries of a large corporation (i.e., U.S. Surgical) or privately held corporations, whose sales revenue or volume data is, therefore, not readily available or determinable. In addition, lymphatic mapping does not currently have a separate reimbursement code in most healthcare systems. As such, determining trends in the actual number of procedures being performed is difficult. We believe, based on our understanding of EES' success rate in competitive bid situations, that our market share has remained relatively constant or increased slightly in light of changes in the competitive landscape over the past few years. As we have discussed, we believe that current sales levels indicate that some prospective customers may be waiting on the results of important international clinical trials prior to adoption the ILM procedure and purchasing a gamma detection device. We expect the results from these trials, when announced, will likely have a positive impact on sales volumes. We believe our intellectual property portfolio will be a barrier to competitive products; we cannot assure you, however, that competitive products will not be developed and be successful in eroding our market share or the prices we receive for our gamma detection devices. See also Risk Factors.

### Gamma Detection Radiopharmaceuticals

We do not believe there are any directly competitive intraoperative diagnostic radiopharmaceuticals with RIGSCAN CR49 that would be used intraoperatively in the colorectal cancer application that RIGSCAN CR49 is initially targeted for. There are other radiopharmaceuticals that are used as preoperative imaging agents; however, we are unaware of any that could be used as a real-time diagnostic aid during surgery such as RIGSCAN CR49. Surgeons who practice the lymphatic mapping procedure that LYMPHOSEEK is intended for currently use other radiopharmaceuticals such as sulphur-colloid compound in the U.S. and other

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colloid compounds in other markets. However, these drugs are being used "off-label" (i.e., they are

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not specifically indicated for use as a lymphatic targeting agent). As such, we believe that LYMPHOSEEK, if ultimately approved, would be the first drug specifically labeled for use as a lymphatic targeting agent.

### Blood Flow Measurement Devices

There are several technologies on the market that measure or claim to measure indices of blood flow. These products can be categorized as devices that measure blood flow directly and devices that only obtain an estimation of flow conditions.

#### Direct Blood Flow Measurement Devices

- Transit Time Ultrasound (TT) Flowmetry is the leading modality in the operating room today. TT systems monitor blood flow invasively, and are restricted to isolated vessels. They require probe adaptation to the vessel size, and do not provide additional vascular parameters. The technology requires the operator to encircle the blood vessel with a probe that includes two ultrasound transmitters/receivers on one side, and a mirror reflector on the opposite side of the vessel. By measuring the transit time of the ultrasound beam in the upstream and downstream directions, volume blood flow estimates can be evaluated.
- Electromagnetic Flowmeters (EMF) are probably the oldest modality to quantify blood flow (other than timed collection). These devices monitor blood flow invasively, are impractical for multiple readings on different vessels, require precise sizing of probes to blood vessels, and do not provide additional hemodynamic parameters. The technology requires the operator to encircle the blood vessel with an electromagnetic probe. The probe generates an electromagnetic field, and the voltage measured due to the blood flow is translated into volume flow estimates. In practice, however, this technology is generally considered outdated.
- Doppler technology has been around for several decades, and is being widely used in non-invasive vascular diagnostics. Duplex ultrasound systems have the potential to measure blood flow non-invasively. Duplex systems are designed for imaging the anatomical severity of pathology. This method is technician-dependent, cumbersome, inaccurate and does not offer monitoring capabilities. However, plain Doppler systems provide only blood flow velocity rather than volume flow.

#### Indirect Blood Flow Measurement Devices

- Cardiac Output (CO) Monitors include various means to monitor CO such as Thermal Dilution, Bio Impedance, and the Fick Method. These methods are either invasive or indirect in their measurement. Thermal Dilution, primarily through pulmonary artery catheterization, is the standard of care today for cardiac output measurements. This technology is not applicable to other intraoperative blood flow applications. The patient is injected with cold saline at a fixed temperature, and a temperature-sensitive transducer that is placed at the site of interest (usually the pulmonary artery) measures the time to return to baseline temperature, which is proportional to the blood flow rate. There are many limitations to this technology, including the relatively large inaccuracies of cardiac output measurements, the fact that it is not

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truly real-time, and the fact that this method is highly invasive, and is being linked to increased morbidity and mortality (JAMA, Connors et al., 1996).

- Computed Tomography, Magnetic Resonance Imaging and Single Photon Emission Computed Tomography techniques show target organ perfusion, but lack the ability to monitor or to provide real-time information. They are technician-dependent, impractical for bedside usage and very expensive.
- Laser Doppler Flowmeters monitor skin blood flow non-invasively. They are applicable only to superficial and tiny vessels and do not provide additional hemodynamic parameters.

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- Transcranial Doppler (TCD) monitors cerebral blood velocity rather than direct blood flow. TCD is non-invasive and provides continuous measurement of blood flow velocity in the vessels of the brain. TCD is technician-dependent and cannot be used on every patient.
- Plethysmography indirectly measures an index of blood flow and is limited primarily to limb assessment. Measurement depends upon many factors and output is accordingly inaccurate.
- Jugular Bulb Saturation measures the efficiency of oxygen use by the brain. It is invasive, and provides global results.
- NIRS is a non-invasive method utilizing near infrared spectroscopy to provide regional perfusion in the brain.

### Potentially Competitive Blood Flow Measurement Devices

Cardiosonix products are designed to address blood flow measurement across a variety of clinical and surgical settings, and there are a number of companies already in the marketplace that offer products related to blood flow measurement. However, most of these products do not directly compete with Cardiosonix products. The companies that do offer potentially competitive products are, for the most part, smaller, privately held companies, with which we believe we can effectively compete. Indeed, due to our belief in the technical superiority of our products, we believe the existence of competitors will help to educate the marketplace regarding the importance of blood flow measurement. As we have discussed, adoption of blood flow monitoring devices for the measurement of hemodynamic status will likely take an involved education process as it often involves a change in clinical or surgical management. While there is not a clear leader in these markets, the following companies compete most directly with Cardiosonix:

- Intraoperative applications: Carolina Medical, Inc. (EMF), Transonic Systems, Inc. and Medi-Stim AS (TT).
- Neurosurgery applications: HADECO, Hayashi Denki Co., Ltd. (Doppler based), DWL Elektronische Systeme GmbH and Nicolet Biomedical (TCD).
- Critical care monitoring: Deltex Medical Ltd. Arrow International, Inc. (Transesophageal Doppler), and CardioDynamics International Corp. (Bio Impedance).

### PATENTS AND PROPRIETARY RIGHTS

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We regard the establishment of a strong intellectual property position in our technology as an integral part of the development process. We attempt to protect our proprietary technologies through patents and intellectual property positions, in the United States as well as major foreign markets. Specifically, twenty instrument patents have been issued in the United States as well as major foreign markets protect our ILM technology.

Cardiosonix has also applied for patent coverage for the key elements of its ADBF technology in the EU and the U.S. The first of the two patents covering Cardiosonix ADBF technology was issued in the U.S. in January 2003 and claims for the second patent have been allowed. Two patents have been filed in the EU and the claims of one patent have been allowed and the claims of the second patent are in the late stage of review by the relevant governing bodies.

Lymphoseek is also the subject of patent applications in the United States and certain major foreign markets. The first composition of matter patent covering Lymphoseek was issued in the U.S. in June 2002. The claims of the composition of matter patent covering Lymphoseek have been allowed in the EU.

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We continue to attempt to maintain proprietary protection for the products related to RIGS and ACT in major global markets such as the U.S. and the EU, which although not currently integral to our near-term business plans, may be important to a potential RIGS or ACT development partner. Certain aspects of our RIGS technology are claimed in the United States in U.S. Patent No. 4,782,840, which expires in 2005, unless extended. In addition to the RIGS patent, composition of matter patents that have been issued in the U.S. and EU cover the antibodies used in clinical studies. The most recent of these patents issued in 2003.

The patent position of biotechnology and medical device firms, including our company, generally is highly uncertain and may involve complex legal and factual questions. Potential competitors may have filed applications for, or may have been issued patents, or may obtain additional patents and proprietary rights relating to products or processes in the same area of technology as that used by our company. The scope and validity of these patents and applications, the extent to which we may be required to obtain licenses thereunder or under other proprietary rights, and the cost and availability of licenses are uncertain. We cannot assure you that our patent applications will result in additional patents being issued or that any of our patents will afford protection against competitors with similar technology; nor can we assure you that any of our patents will not be designed around by others or that others will not obtain patents that we would need to license or design around. See also Risk Factors.

We also rely upon unpatented trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets, or disclose such technology, or that we can meaningfully protect our rights to our unpatented trade secrets.

We require our employees, consultants, advisers, and suppliers to execute a confidentiality agreement upon the commencement of an employment, consulting or manufacturing relationship with us. The agreement provides that all confidential information developed by or made known to the individual during the course of the relationship will be kept confidential and not disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual will be the exclusive property of our company. We cannot assure you, however, that these agreements will provide meaningful protection for our trade secrets in the event of an unauthorized use or disclosure of such information.

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### GOVERNMENT REGULATION

Most aspects of our business are subject to some degree of government regulation in the countries in which we conduct our operations. As a developer, manufacturer and marketer of medical products, we are subject to extensive regulation by, among other governmental entities, the FDA and the corresponding state, local and foreign regulatory bodies in jurisdictions in which our products are sold. These regulations govern the introduction of new products, the observance of certain standards with respect to the manufacture, safety, efficacy and labeling of such products, the maintenance of certain records, the tracking of such products and other matters.

Failure to comply with applicable federal, state, local or foreign laws or regulations could subject us to enforcement action, including product seizures, recalls, withdrawal of marketing clearances, and civil and criminal penalties, any one or more of which could have a material adverse effect on our business. We believe that we are in substantial compliance with such governmental regulations. However, federal, state, local and foreign laws and regulations regarding the manufacture and sale of medical devices are subject to future changes. We cannot assure you that such changes will not have a material adverse effect on our company.

For some products, and in some countries, government regulation is significant and, in general, there is a trend toward more stringent regulation. In recent years, the FDA and certain foreign regulatory bodies have pursued a more rigorous enforcement program to ensure that regulated businesses, like ours, comply with applicable laws and regulations. We devote significant time, effort and expense addressing

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the extensive governmental regulatory requirements applicable to our business. To date, we have not received any notifications or warning letters from the FDA or any other regulatory bodies of alleged deficiencies in our compliance with the relevant requirements, nor have we recalled or issued safety alerts on any of our products. However, we cannot assure you that a warning letter, recall or safety alert, if it occurred, would not have a material adverse effect on our company.

In the early to mid 1990s, the review time by the FDA to clear medical products for commercial release lengthened and the number of marketing clearances decreased. In response to public and congressional concern, the FDA Modernization Act of 1997 (the 1997 Act) was adopted with the intent of bringing better definition to the clearance process for new medical products. While FDA review times have improved since passage of the 1997 Act, we cannot assure you that the FDA review process will not continue to delay our company's introduction of new products in the U.S. in the future. In addition, many foreign countries have adopted more stringent regulatory requirements that also have added to the delays and uncertainties associated with the release of new products, as well as the clinical and regulatory costs of supporting such releases. It is possible that delays in receipt of, or failure to receive, any necessary clearance for our new product offerings could have a material adverse effect on our business, financial condition or results of operations.

While we are unable to predict the extent to which our business may be affected by future regulatory developments, we believe that our substantial experience dealing with governmental regulatory requirements and restrictions on our operations throughout the world, and our development of new and improved products, should enable us to compete effectively within this environment.

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### Gamma Detection and Blood Flow Measurement Devices

As a manufacturer of medical devices sold in various global markets, we are required to manufacture the devices under quality system regulations (QSR) and maintain appropriate technical files and quality records. Our medical devices are regulated in the United States by the FDA. Our medical devices are regulated in the EU according to the Medical Device Directive (93/42/EEC). Under this regulation, we must obtain CE Mark status for all products exported to the EU.

Our initial generation gamma detection instruments received 510(k) marketing clearance from the FDA in December 1986 with modified versions receiving similar clearances in 1992 through 1997. In 1998, the FDA reclassified "nuclear uptake detectors" as being exempt from the 510(k) process. We believe the NEO2000 device is exempt from the 510(k) process because it is substantially equivalent to previously cleared predecessor devices. We obtained the CE Mark for the neo2000 device in January 1999, and therefore, must continue to manufacture the devices under a quality system compliant to the requirements of ISO 9001/EN 46001 and maintain appropriate technical files. We maintain a license to import our gamma devices into Canada, and therefore must continue to manufacture the devices under a quality system compliant to the requirements of ISO 13485 and CMDCAS.

Cardiosonix has received 510(k) and CE mark clearance to market the QUANTIX/ND device in the U.S. and EU for non-invasive applications. The QUANTIX/OR has also received CE Mark clearance to market in the EU and 510(k) clearance in the U.S. Our distribution partners in certain foreign markets other than the EU are seeking marketing clearances, as required, for both the QUANTIX/ND and QUANTIX/OR. We intend to submit additional applications for clearance or amendments, as appropriate, for the QUANTIX/TE in the future.

### Gamma Detection Radiopharmaceuticals (LYMPHOSEEK and RIGS)

Our radiolabeled targeting agents and biologic products, if developed, would require a regulatory license to market by the FDA and by comparable agencies in foreign countries. The process of obtaining regulatory licenses and approvals is costly and time consuming, and we have encountered significant impediments and delays related to our previously proposed biologic products.

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The process of completing pre-clinical and clinical testing, manufacturing validation and submission of a marketing application to the appropriate regulatory bodies usually takes a number of years and requires the expenditure of substantial resources, and we cannot assure you that any approval will be granted on a timely basis, if at all. Additionally, the length of time it takes for the various regulatory bodies to evaluate an application for marketing approval varies considerably, as does the amount of preclinical and clinical data required to demonstrate the safety and efficacy of a specific product. The regulatory bodies may require additional clinical studies that may take several years to perform. The length of the review period may vary widely depending upon the nature and indications of the proposed product and whether the regulatory body has any further questions or requests any additional data. Also, the regulatory bodies will likely require postmarketing reporting and surveillance programs to monitor the side effects of the products. We cannot assure you that any of our potential drug or biologic products will be approved by the regulatory bodies or approved on a timely or accelerated basis, or that any approvals received will not subsequently be revoked or modified.

In addition to regulations enforced by the FDA, the manufacture, distribution, and use of radioactive targeting agents, if developed, are also subject to regulation by the Nuclear Regulatory Commission (NRC), the Department of

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Transportation and other federal, state, and local government authorities. We, or our manufacturer of the radiolabeled antibodies, must obtain a specific license from the NRC to manufacture and distribute radiolabeled antibodies, as well as comply with all applicable regulations. We must also comply with Department of Transportation regulations on the labeling and packaging requirements for shipment of radiolabeled antibodies to licensed clinics, and must comply with federal, state, and local governmental laws regarding the disposal of radioactive waste. We cannot assure you that we will be able to obtain all necessary licenses and permits and be able to comply with all applicable laws. The failure to obtain such licenses and permits or to comply with applicable laws would have a materially adverse effect on our business, financial condition, and results of operations.

### EMPLOYEES

As of March 15, 2004, we had 19 full-time employees, including those of our subsidiary, Cardiosonix. We consider our relations with our employees to be good.

### RISK FACTORS

An investment in our common stock is highly speculative, involves a high degree of risk, and should be made only by investors who can afford a complete loss. Investors should carefully consider the following risk factors, together with the other information in this Annual Report on Form 10-KSB, including our financial statements and the related notes, before you decide to buy our common stock. Our most significant risks and uncertainties are described below; however, they are not the only risks we face. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading of our common stock could decline, and you may lose all or part of your investment therein.

We have suffered significant operating losses for several years in our history and we may not be able to again achieve profitability.

We had an accumulated deficit of approximately \$123 million as of December 31, 2003. Although we were profitable in 2000 and in 2001, we incurred substantial losses in the years prior to that, and in 2002 and 2003. The deficit resulted because we expended more money in the course of researching, developing and enhancing our technology and products and establishing our marketing and administrative organizations than we generated in revenues. We expect to continue to incur significant operating expenses in the foreseeable future, primarily related to the completion of development and commercialization of the Cardiosonix product line but also potentially related to RIGS and LYMPHOSEEK. As a result, we are sustaining substantial operating and net losses, and it is possible that we will never be able to sustain or develop the revenue levels necessary to again attain profitability.

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Our products may not achieve the broad market acceptance they need in order to be a commercial success.

Widespread use of our gamma detection devices is currently limited to a surgical procedure (ILM) used in the treatment and diagnosis of two primary types of cancer: melanoma and breast cancer. The success of our gamma detection devices greatly depends on the medical community's acceptance of ILM, and on our devices for use in ILM as a reliable, safe and cost effective alternative to current treatments and procedures. The adoption rate for ILM appears to be leveling off and may not meet our growth expectations. Although we continue to believe that ILM has significant advantages over other currently competing procedures,

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broad-based clinical adoption of ILM will likely not occur until after the completion of ongoing international trials related to breast cancer. Even if the results of these trials are positive, we cannot assure you that ILM will attain rapid and widespread acceptance. Our efforts and those of our marketing and distribution partners may not result in significant demand for our products, and the current demand for our products may decline.

Our future success now also greatly depends on the success of the Cardiosonix product line. Cardiosonix' products are just beginning to be marketed commercially. The market for these products is in an early stage of development and may never fully develop as we expect. The long-term commercial success of the Cardiosonix product line will require widespread acceptance of our products as safe, efficient and cost-effective. Widespread acceptance would represent a significant change in medical practice patterns. Other cardiac monitoring procedures, such as pulmonary artery catheterization, are generally accepted in the medical community and have a long standard of use. It is possible that the Cardiosonix product line will never achieve the broad market acceptance necessary to become a commercial success.

We rely on third parties for the worldwide marketing and distribution of our gamma detection devices, who may not be successful in selling our products.

We currently distribute our gamma detection devices in most global markets through two partners who are solely responsible for marketing and distributing these products. The partners assume direct responsibility for business risks related to credit, currency exchange, foreign tax laws or tariff and trade regulation. While we believe that our distribution partners intend to continue to aggressively market our products, we cannot assure you that the distribution partners will succeed in marketing our products on a global basis. We may not be able to maintain satisfactory arrangements with our marketing and distribution partners, who may not devote adequate resources to selling our gamma detection devices. If this happens, we may not be able to successfully market our products, which would decrease our revenues.

We do not have experience in marketing blood flow devices and we have not yet established long-term strategic relationships with a significant number of potential marketing partners.

We completed the Cardiosonix acquisition on December 31, 2001, and to date we have limited marketing and distribution experience with the QUANTIX line of blood flow products covering only a limited number of countries. We believe the adoption path for Cardiosonix' products will be similar to that of our gamma detection devices, but we have no direct experience in marketing or selling blood flow measurement devices and will likely be working with pricing structures such as per-use or leasing with which we have little direct experience. Further, we may not be successful in creating the necessary infrastructure, either internally or through third parties, to support the successful marketing and sales of Cardiosonix products.

We may have difficulty raising additional capital, which could deprive us of necessary resources.

We expect to continue to devote capital resources to fund research and development and to maintain existing and secure new manufacturing capacity. In order to support the initiatives envisioned in our business plan, we may need to raise additional funds through the sale of assets, public or private financing, collaborative relationships or other arrangements. Our ability to raise additional financing depends on many factors beyond our control, including the state of capital markets, the market price of



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our common stock and the development or prospects for development of competitive technology by others. Because our common stock is not listed on a major stock market, many investors may not be willing or allowed to purchase it or may demand steep discounts. Sufficient additional financing may not be available to us or may be available only on terms that would result in further dilution to the current owners of our common stock. At current market prices, the limited number of shares we have available to sell severely limits our ability to use equity as a method of raising capital. If we are unable to raise additional funds when we need them, we may have to severely curtail our operations.

The sale of the shares of common stock acquired in private placements could cause the price of our common stock to decline.

During 2003, we completed several financings in which we issued common stock, warrants and other securities convertible into common stock to certain private investors and as required under the terms of those transactions, we filed a registration statement with the United States Securities and Exchange Commission (SEC) under which the investors may resell common stock acquired in these transactions to the public. We have also filed a registration statement covering the resale of common stock issued to former stockholders of Cardiosonix in connection with our acquisition of that business.

The selling stockholders under these registration statements may sell none, some or all of the shares of common stock acquired from us, as well as common stock acquired on the exercise of the warrants and convertible securities held by them. We have no way of knowing whether the selling stockholders will sell the shares covered by these registration statements. Depending upon market liquidity at the time, a sale of shares covered by these registration statements at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock under this prospectus, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

We rely on third parties to manufacture our products and our business will suffer if they do not perform.

We rely on independent contract manufacturers for the manufacture of our current line of gamma detection systems and for our QUANTIX line of blood flow monitoring products. Our business will suffer if our contract manufacturers have production delays or quality problems. Furthermore, medical device manufacturers are subject to the QSR regulations of the FDA, international quality standards, and other regulatory requirements. If our contractors do not operate in accordance with regulatory requirements and quality standards, our business will suffer. We use or rely on components and services used in our devices that are provided by sole source suppliers. The qualification of additional or replacement vendors is time consuming and costly. If a sole source supplier has significant problems supplying our products, our sales and revenues will be hurt until we find a new source of supply. In addition, our distribution agreement with EES for gamma devices contains failure to supply provisions, which, if triggered, could have a significant negative impact on our business.

We may lose out to larger and better-established competitors.

The medical device and biotechnology industries are intensely competitive. Some of our competitors have significantly greater financial, technical, manufacturing, marketing and distribution resources as well as greater experience in the medical device industry than we have. The particular medical conditions our product lines address can also be addressed by other medical devices, procedures or drugs. Many of these alternatives are widely accepted by physicians and have a long history of use. Physicians may use our competitors'

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products and/or our products may not be competitive with other technologies. If these things happen, our sales and revenues will decline. In addition, our current and potential competitors may establish cooperative relationships with large medical equipment companies to gain access to greater research and development or marketing resources. Competition may result in price reductions, reduced gross margins and loss of market share.

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Our products may be displaced by newer technology.

The medical device and biotechnology industries are undergoing rapid and significant technological change. Third parties may succeed in developing or marketing technologies and products that are more effective than those developed or marketed by us, or that would make our technology and products obsolete or non-competitive. Additionally, researchers could develop new surgical procedures and medications that replace or reduce the importance of the procedures that use our products. Accordingly, our success will depend, in part, on our ability to respond quickly to medical and technological changes through the development and introduction of new products. We may not have the resources to do this. If our products become obsolete and our efforts to develop new products do not result in any commercially successful products, our sales and revenues will decline.

We are in a highly regulated business and could face severe problems if we do not comply with all regulatory requirements in the global markets in which our products are sold.

The FDA regulates our products in the United States. Foreign countries also subject our products to varying government regulations. In addition, such regulatory authorities may impose limitations on the use of our products. FDA enforcement policy strictly prohibits the marketing of FDA cleared medical devices for unapproved uses. Within the European Union, our products are required to display the CE Mark in order to be sold. We have obtained FDA clearance to market and European certification to display the CE Mark on our current line of gamma detection systems and on two of Cardiosonix' products, the QUANTIX/ND and QUANTIX/OR. We may not be able to obtain clearance to market for any new products in a timely manner, or at all. Failure to comply with these and other current and emerging regulatory requirements in the global markets in which our products are sold could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance for devices, withdrawal of clearances, and criminal prosecution.

Our intellectual property may not have or provide sufficient legal protections against infringement or loss of trade secrets.

Our success depends, in part, on our ability to secure and maintain patent protection, to preserve our trade secrets, and to operate without infringing on the patents of third parties. While we seek to protect our proprietary positions by filing United States and foreign patent applications for our important inventions and improvements, domestic and foreign patent offices may not issue these patents. Third parties may challenge, invalidate, or circumvent our patents or patent applications in the future. Competitors, many of which have significantly more resources than we have and have made substantial investments in competing technologies, may apply for and obtain patents that will prevent, limit, or interfere with our ability to make, use, or sell our products either in the United States or abroad.

In the United States, patent applications are secret until patents issue, and in foreign countries, patent applications are secret for a time after filing.

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Publications of discoveries tend to significantly lag the actual discoveries and the filing of related patent applications. Third parties may have already filed applications for patents for products or processes that will make our products obsolete or will limit our patents or invalidate our patent applications.

We typically require our employees, consultants, advisers and suppliers to execute confidentiality and assignment of invention agreements in connection with their employment, consulting, advisory, or supply relationships with us. They may breach these agreements and we may not obtain an adequate remedy for breach. Further, third parties may gain access to our trade secrets or independently develop or acquire the same or equivalent information.

Agencies of the United States government conducted some of the research activities that led to the development of antibody technology that some of our proposed antibody-based surgical cancer detection products use. When the United States government participates in research activities, it retains rights that include the right to use the technology for governmental purposes under a royalty-free license, as well as

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rights to use and disclose technical data that could preclude us from asserting trade secret rights in that data and software.

Conditions in Israel may affect the operations of Cardiosonix and may limit our ability to complete development of its products.

Our Cardiosonix subsidiary is incorporated in Israel, and its offices and research and development facilities are located there. In concert with the plan to transfer or manufacturing of the QUANTIX products to a contract manufacturer located in the United States, certain manufacturing and development activities underway in Israel have been or will be curtailed or discontinued. While we have reduced our activities in Israel, continued adverse political, economic and military conditions in Israel may directly affect our operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Despite past progress towards peace between Israel and its Arab neighbors, the future of these peace efforts is uncertain. Any armed conflict, political instability or continued violence in the region could have a negative effect on the activities of Cardiosonix and the completion of development and commercialization of our blood flow monitoring products.

The government grants Cardiosonix has received for research and development expenditures restrict our ability to manufacture blood flow monitoring products and transfer technologies outside of Israel and require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received together with interest and penalties, and may be subject to criminal charges.

Cardiosonix received grants from the government of Israel through the Office of the Chief Scientist of the Ministry of Industry and Trade for the financing of a portion of its research and development expenditures associated with our blood flow monitoring products. From 1998 to 2001, Cardiosonix received grants totaling \$775,000 from the OCS. The terms of the OCS grants may affect our efforts to transfer manufacturing of products developed using these grants outside of Israel without special approvals. The OCS issued a letter to Neoprobe in December 2001, prior to the acquisition of Cardiosonix, consenting to the transfer of manufacturing as long as Neoprobe consented to the terms of the OCS statutes under Israeli law. As a result of our efforts to transfer a significant portion of the manufacture of our blood flow products out of Israel, we will

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likely be required to pay an increased amount of royalties, which may be up to 300% of the grant amount, depending on the manufacturing volume that is performed outside of Israel. This may impair our ability to effectively outsource manufacturing or engage in similar arrangements for those products or technologies. In addition, if we fail to comply with any of the conditions imposed by the OCS, we may be required to refund any grants previously received together with interest and penalties, and may be subject to criminal charges. In recent years, the government of Israel has accelerated the rate of repayment of OCS grants and may further accelerate them in the future.

Our product sales may be adversely affected by healthcare pricing regulation and reform activities.

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the United States, comprehensive programs have been proposed that seek to increase access to healthcare for the uninsured, control the escalation of healthcare expenditures within the economy and use healthcare reimbursement policies to balance the federal budget.

We expect that Congress and state legislatures will continue to review and assess healthcare proposals, and public debate of these issues will likely continue. We cannot predict which, if any, of such reform proposals will be adopted and when they might be adopted. Other countries also are considering healthcare reform. Significant changes in healthcare systems could have a substantial impact on the manner in which we conduct our business and could require us to revise our strategies.

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We could be damaged by product liability claims.

Our products are used or intended to be used in various clinical or surgical procedures. If one of our products malfunctions or a physician misuses it and injury results to a patient or operator, the injured party could assert a product liability claim against our company. We currently have product liability insurance with a \$10 million per occurrence limit, which we believe is adequate for our current activities. However, we may not be able to continue to obtain insurance at a reasonable cost. Furthermore, insurance may not be sufficient to cover all of the liabilities resulting from a product liability claim, and we might not have sufficient funds available to pay any claims over the limits of our insurance. Because personal injury claims based on product liability in a medical setting may be very large, an underinsured or an uninsured claim could financially damage our company.

We may have trouble attracting and retaining qualified personnel and our business may suffer if we do not.

Our business has experienced developments the past two years that have resulted in several significant changes in our strategy and business plan, including the shifting of resources to support our current product initiatives and downsizings to what we consider to be the minimal support structure necessary to operate a publicly traded company. Our management will need to remain flexible to support our business model over the next few years. However, losing members of the Neoprobe management team could have an adverse effect on our operations. Our success depends on our ability to attract and retain technical and management personnel with expertise and experience in the medical device business. The competition for qualified personnel in the medical device industry is intense and we may not be successful in hiring or retaining the requisite personnel. If we are unable to attract and retain qualified technical and management personnel, we will suffer diminished chances of future success.

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Under the terms of our 2003 bridge financings, we have or may be required to grant partial or complete liens on substantially all of our assets.

Under the terms of the bridge loan agreements we entered into with an unaffiliated investor and our President and CEO in 2003, we granted them a security interest in certain of our assets, including our intellectual property. We believe this is customary in such transactions. The unaffiliated investor converted his loan to equity in early 2004, so only the security interest held by our President and CEO remains in effect. In the event of a default by us under the terms of the loan, the holder could foreclose on the security interest in our assets. If this were to happen, we may be required to file a petition under Chapter 11 of the Bankruptcy Code seeking protection, or file a petition under Chapter 7 and liquidate.

Our common stock is traded over the counter, which may deprive stockholders of the full value of their shares.

Our common stock is quoted via the National Association of Securities Dealers' Over The Counter Bulletin Board (OTCBB). As such, our common stock may have fewer market makers, lower trading volumes and larger spreads between bid and asked prices than securities listed on an exchange such as the New York Stock Exchange or the Nasdaq Stock Market. These factors may result in higher price volatility and less market liquidity for the common stock.

A low market price may severely limit the potential market for our common stock.

Our common stock is currently trading at a price substantially below \$5.00 per share, subjecting trading in the stock to certain SEC rules requiring additional disclosures by broker-dealers. These rules generally apply to any non-NASDAQ equity security that has a market price share of less than \$5.00 per share, subject to certain exceptions (a "penny stock"). Such rules require the delivery, prior to any penny stock transaction, of a disclosure schedule explaining the penny stock market and the risks associated therewith and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and institutional or wealthy investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the

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purchaser's written consent to the transaction prior to the sale. The broker-dealer also must disclose the commissions payable to the broker-dealer, current bid and offer quotations for the penny stock and, if the broker-dealer is the sole market maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Such information must be provided to the customer orally or in writing before or with the written confirmation of trade sent to the customer. Monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. The additional burdens imposed upon broker-dealers by such requirements could discourage broker-dealers from effecting transactions in our common stock.

The price of our common stock has been highly volatile due to several factors that will continue to affect the price of our stock.

Our common stock has traded as low as \$0.10 per share and as high as \$0.89 per share in the last twelve months. Some of the factors leading to the volatility include:

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- price and volume fluctuations in the stock market at large which do not relate to our operating performance;
- fluctuations in our operating results;
- financing arrangements we may enter that require the issuance of a significant number of shares in relation to the number of shares currently outstanding;
- announcements of technological innovations or new products which we or our competitors make;
- FDA and/or international regulatory actions;
- developments with respect to patents or proprietary rights;
- public concern as to the safety of products that we or others develop; and,
- fluctuations in market demand for and supply of our products.

An investor's ability to trade our common stock may be limited by trading volume.

Until recently, the trading volume for our common stock has been relatively limited. A consistently active trading market for our common stock may not occur on the OTCBB. The average daily trading volume for our common stock on the OTCBB for the twelve-month period ended March 15, 2004 was approximately 359,300 shares. Daily volume during that period ranged from 0 shares to 4,440,870 shares.

Our stockholder rights plan, some provisions of our organizational and governing documents and an agreement with selling stockholders, may have the effect of deterring third parties from making takeover bids for control of our company or may be used to hinder or delay a takeover bid.

Our certificate of incorporation authorizes the creation and issuance of "blank check" preferred stock. Our Board of Directors may divide this stock into one or more series and set their rights. The Board of Directors may, without prior stockholder approval, issue any of the shares of "blank check" preferred stock with dividend, liquidation, conversion, voting or other rights, which could adversely affect the relative voting power or other rights of the common stock. Preferred stock could be used as a method of discouraging, delaying, or preventing a take-over of our company. If we issue "blank check" preferred stock, it could have a dilutive effect upon our common stock. This would decrease the chance that our stockholders would realize a premium over market price for their shares of common stock as a result of a takeover bid.

Because we will not pay dividends, stockholders will only benefit from owning common stock if it appreciates.

We have never paid dividends on our common stock and we do not intend to do so in the foreseeable future. We intend to retain any future earnings to finance our growth. Accordingly, any potential investor who anticipates the need for current dividends from his investment should not purchase our common stock.

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This report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

- general economic and business conditions, both nationally and in our markets,
- our history of losses,
- our expectations and estimates concerning future financial performance, financing plans and the impact of competition,
- our ability to implement our growth strategy,
- anticipated trends in our business,
- advances in technologies, and
- other risk factors set forth under "Risk Factors" in this report.

In addition, in this report, we use words such as "anticipates," "believes," "plans," "expects," "future," "intends," and similar expressions to identify forward-looking statements.

We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

### ITEM 2. DESCRIPTION OF PROPERTY

We currently lease our office at 425 Metro Place North, Dublin, Ohio. We executed a lease agreement, commencing on September 1, 2003 and ending in September 2006, with the landlord of these facilities for approximately 9,000 square feet. The lease provides for a monthly base rent of approximately \$6,200 in 2004. We must also pay a pro-rata portion of the operating expenses and real estate taxes of the building. We believe these facilities are in good condition and will be adequate for our needs for the foreseeable future.

Our subsidiary, Cardiosonix Ltd., currently leases its office in the Millennium Building at 3 Ha'Tidhar Street, Ra'anana, Israel. The lease covers approximately 470 square meters of space and expires in April 2005. The lease provides for a monthly base rent of \$2,400 through the expiration of the lease.

### ITEM 3. LEGAL PROCEEDINGS

None.

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

None.

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### ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock trades on the OTCBB under the trading symbol NEOP. The prices set forth below reflect the quarterly high, low and closing sales prices for shares of our common stock during the last two fiscal years as reported by Reuters Limited. These quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions.

	HIGH	LOW	CLOSE
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Fiscal Year 2003:			
First Quarter	\$ 0.17	\$ 0.10	\$ 0.11
Second Quarter	0.26	0.10	0.17
Third Quarter	0.50	0.14	0.29
Fourth Quarter	0.43	0.24	0.31
Fiscal Year 2002:			
First Quarter	\$ 0.55	\$ 0.35	\$ 0.38
Second Quarter	0.42	0.25	0.28
Third Quarter	0.30	0.08	0.12
Fourth Quarter	0.31	0.05	0.13

As of March 15, 2004, we had approximately 853 holders of common stock of record.

We have not paid any dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. We intend to retain any earnings to finance the growth of our business. We cannot assure you that we will ever pay cash dividends. Whether we pay cash dividends in the future will be at the discretion of our Board of Directors and will depend upon our financial condition, results of operations, capital requirements and any other factors that the Board of Directors decides are relevant. See Management's Discussion and Analysis of Financial Condition and Results of Operations, below.

#### Recent Sales of Unregistered Securities

The following sets forth certain information regarding the sale of equity securities of our company during the period covered by this report that were not registered under the Securities Act of 1933 (the Securities Act).

In March 2003 and March 2002, our Board of Directors authorized the issuance of 100,327 and 53,116 shares of common stock, respectively, to the trustees of our 401(k) employee benefit plan (the Plan) without registration. Such issuance is exempt from registration under the Securities Act under Section 3(a)(2). The Plan is a pension, profit sharing or stock bonus plan that is qualified under Section 401 of the Internal Revenue Code. The assets of the Plan are held in a single trust fund for the benefit of our employees, which does not hold assets for the benefit of the employees of any other employer. All of the contributions to the Plan from our employees have been invested in assets other than our common stock. We have contributed all of the Neoprobe common stock held by the Plan as a matching contribution that has been less in value at the time it was contributed to the Plan than the employee contributions that it matches.

On November 19, 2001, we entered into a common stock purchase agreement with an investment fund, Fusion Capital Fund II, LLC (Fusion) for the issuance and purchase of our common stock. Under the stock purchase agreement, Fusion committed to purchase up to \$10 million of our common stock over a forty-month



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period that commenced in May 2002. A registration statement registering for resale up to 5 million shares of our common stock was declared effective on April 15, 2002. Under the terms of the agreement, we can request daily drawdowns,

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subject to a daily base amount currently set at \$12,500. The number of shares we are to issue to Fusion in return for that money is based on the lower of (a) the closing sale price for our common stock on the day of the draw request or (b) the average of the three lowest closing sales prices for our common stock during a twelve-day period prior to the draw request. However, no shares may be sold to Fusion at lower than a floor price currently set at \$0.30, which may be reduced by us, but in no case below \$0.20 without Fusion's prior consent. Upon execution of the common stock purchase agreement, we issued 449,438 shares of our common stock to Fusion as a commitment fee. During the second half of 2003, we sold Fusion a total of 473,869 shares of common stock and realized net proceeds of \$143,693. In addition, we issued Fusion another 6,462 shares of common stock for commitment fees due to Fusion related to the sales of our common stock to them during the second half of 2003. During the first quarter of 2004 to date, we sold Fusion a total of 2,100,000 shares of common stock and realized proceeds of \$1,271,334. We issued Fusion 57,140 shares of common stock for commitment fees due to Fusion related to the sales of our common stock to them during the first quarter of 2004. The issuances of the shares of common stock to Fusion pursuant to the common stock purchase agreement were exempt from registration under Sections 4(2) and 4(6) of the Securities Act and Regulation D.

On December 31, 2001, we acquired 100 percent of the outstanding common shares of Cardiosonix Ltd. (Cardiosonix), formerly Biosonix Ltd., an Israeli company limited by shares, from the Cardiosonix selling stockholders pursuant to the terms of a stock purchase agreement dated November 29, 2001 (the Stock Purchase Agreement). Under the terms of the Stock Purchase Agreement, at closing we issued to the selling stockholders 9,714,737 shares of shares of our common stock, \$.001 par value. On December 30, 2002, we issued an additional 2,085,826 shares of common stock to the selling stockholders due to the achievement of a milestone involving Cardiosonix product development activity. The issuance of the shares of common stock to the selling stockholders was exempt from registration under Section 4(2) of the Securities Act and Regulation D. As required under the terms of the Stock Purchase Agreement, in June 2003 we filed a registration statement under which the Cardiosonix selling shareholders may resell their common stock to the public.

During April 2003, we completed a bridge loan agreement with our President and CEO, David Bupp. Under the terms of the agreement, Mr. Bupp advanced us \$250,000. In consideration for the loan, we issued Mr. Bupp 375,000 warrants, expiring in April 2008, to purchase shares of our common stock at an exercise price of \$0.13 per share. Interest accrues on the note at the rate of 8.5% per annum, payable monthly, and the note was due on June 30, 2004. On March 8, 2004, the due date of the note to Mr. Bupp was extended to June 30, 2005. In exchange for extending the due date of the note, we issued Mr. Bupp an additional 375,000 warrants, expiring in March 2009, to purchase our common stock at an exercise price of \$0.50 per share. The issuances of the note and warrants to Mr. Bupp were exempt from registration under Sections 4(2) and 4(6) of the Securities Act and Regulation D.

During April 2003, we also completed a convertible bridge loan agreement with Donald E. Garlikov for an additional \$250,000. In consideration for the loan, we issued Mr. Garlikov 500,000 warrants, expiring in April 2008, to purchase shares of our common stock at an exercise price of \$0.13 per share. Under the terms of the agreement, the note bore interest at 9.5% per annum, payable monthly, and was due on June 30, 2004. During January 2004, Mr. Garlikov converted the entire balance of the note into 1.1 million shares of common stock according to the

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conversion terms of the agreement. Mr. Garlikov's 500,000 warrants remain outstanding. The issuances of the note and warrants to Mr. Garlikov were exempt from registration under Sections 4(2) and 4(6) of the Securities Act and Regulation D. As further consideration for the loans, we agreed to file a registration statement under which Mr. Bupp and Mr. Garlikov could resell to the public shares of common stock issuable on exercise of the warrants and conversion of Mr. Garlikov's note. The shares were included in a registration statement filed in December 2003.

During the second and third quarters of 2003, we engaged the services of two investment banking firms to assist us in raising capital, Alberdale Capital, LLC (Alberdale) and Trautman Wasserman & Company, Inc. (Trautman Wasserman). In exchange for Alberdale's services, we agreed to pay them a monthly retainer of \$10,000, half payable in cash and half payable in common stock, and we agreed to pay them additional compensation upon the successful completion of a private placement of our securities. We

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terminated the agreement with Alberdale effective September 23, 2003, but agreed to issue them a total of 150,943 shares of common stock in payment for one half of their retainer, plus warrants to purchase 78,261 shares of common stock in exchange for their assistance in arranging an accounts receivable financing transaction. The warrants have an exercise price of \$0.28 per share.

In exchange for the services of Trautman Wasserman, we agreed to pay a retainer of \$10,000, payable in cash and stock, and to pay further compensation on successful completion of a private placement. We issued Trautman Wasserman a total of 27,199 shares of common stock in payment for one half of their retainer. The issuances of the shares and warrants to Alberdale and Trautman Wasserman were exempt from registration under Sections 4(2) and 4(6) of the Securities Act and Regulation D.

During October and November 2003, we executed common stock purchase agreements with third parties introduced to us by a third investment banking firm, Rockwood, Inc., for the purchase of 12,173,914 shares of our common stock at a price of \$0.23 per share for net proceeds of \$2.4 million. In addition, we issued the purchasers warrants to purchase 6,086,959 shares of common stock at an exercise price of \$0.28 per share and issued the placement agents warrants to purchase 1,354,348 shares of our common stock on similar terms. All warrants issued in connection with the transaction expire in October 2008. The issuances of the shares and warrants to the purchasers and the placement agents were exempt from registration under Sections 4(2) and 4(6) of the Securities Act and Regulation D. As required under terms of the stock purchase agreements, in December 2003 we filed a registration statement under which the investors and placement agents may resell the shares of common stock to the public.

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### ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read together with our Consolidated Financial Statements and the Notes related to those statements, as well as the other financial information included in this Form 10-KSB. Some of our discussion is forward-looking and involves risks and uncertainties. For information regarding risk factors that could have a material adverse effect on our business, refer to Item 1 of this Form 10-KSB, Description of Business - Risk Factors.

THE COMPANY

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Neoprobe Corporation is a biomedical technology company that provides innovative surgical and diagnostic products that enhance patient care by meeting the critical decision-making needs of healthcare professionals. Prior to the acquisition of Cardiosonix on December 31, 2001, our marketable products were limited to a line of gamma detection devices used in the surgical application of intraoperative lymphatic mapping (ILM). The acquisition of Cardiosonix expanded our potential product offerings beyond the oncology arena and into the area of blood flow measurement and cardiac care. Cardiosonix is in the process of developing and commercializing a unique line of proprietary blood flow monitoring devices for a variety of diagnostic and surgical applications. Cardiosonix has received marketing clearance for two of its products, QUANTIX/ND(TM) and QUANTIX/OR(TM), in Europe and in the U.S.

### OVERVIEW AND OUTLOOK

This Overview and Outlook section contains a number of forward-looking statements, all of which are based on current expectations. Actual results may differ materially. Our financial performance is highly dependent on our ability to continue to generate income and cash flow from our gamma device product line and on our ability to successfully commercialize the blood flow products of our subsidiary, Cardiosonix. We cannot assure you, however, that we will achieve the volume of sales anticipated, or if achieved, that the margin on such sales will be adequate to produce positive operating cash flow. We continue to be optimistic about the longer-term potential for our other proprietary, procedural-based technologies such as LYMPHOSEEK(TM) and RIGS(R) ; however, these technologies are not anticipated to generate any significant revenue for us during 2004.

We are continually assessing our business plan based on events in the marketplace as well as from our product development efforts. We believe that the commercial prospects for Neoprobe have improved significantly over the prior year due to progress we have made in a number of areas. In December 2003, we made significant reductions in the staffing of our subsidiary, Cardiosonix, based on our belief that the development for the QUANTIX/ND and QUANTIX/OR systems were substantially at or near completion. We anticipate marketing expenses in 2004 for our blood flow products will exceed \$1 million. In addition, we expect to incur expenses in 2004 related to radiopharmaceutical development for RIGS and LYMPHOSEEK, although it is difficult to estimate the amount of such expenses until additional feedback is obtained from the FDA and decisions are made regarding internal funding of development for these products versus development through potential partnership relationships. As a result, although we expect to see positive movement in all our lines of business in 2004, we will likely yet show a loss for the year due to our market and product development efforts.

We are not actively engaged in looking for additional investment related to our current device product initiatives; however, we believe that additional funding will be necessary to move the RIGS and LYMPHOSEEK products to commercial viability. We intend to move both RIGS and LYMPHOSEEK forward with internal resources until the regulatory pathway for both products has been clarified. A determination as to the most appropriate way to fund development has not been made at this time, but we are considering both internal and external financing sources. We may decide to develop one or more of these technologies through partnering, joint ventures, etc. As of December 31, 2003, our cash on-hand was \$1.6 million. During 2003, we used \$1.8 million in cash to fund our operations. We believe our currently available capital resources will be adequate to sustain our device operations at current levels into 2005; however, to the extent we decide to fund radiopharmaceutical development internally, we may need to seek additional funding. If we decide to seek additional funding to support the development of radiopharmaceutical products and additional financing is not available when required or is not available on acceptable terms, or we are

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unable to arrange a suitable strategic opportunity, we may need to modify

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our business plan. We cannot assure you that the additional capital we require will be available on acceptable terms, if at all. We cannot assure you that we will be able to successfully commercialize products or that we will achieve significant product revenues from our current or potential new products. In addition, we cannot assure you that we will achieve or sustain profitability in the future.

### OUR OUTLOOK FOR OUR GAMMA DETECTION DEVICE PRODUCTS

Numerous articles have been published in recent years in peer-reviewed journals on the topics of sentinel lymph node biopsy and ILM. Furthermore, a number of thought leaders and cancer treatment institutions have recognized and embraced the technology as standard of care for melanoma and, in some cases, for breast cancer. However, as the melanoma market represents less than 10% of the breast care market, standard of care recognition related to breast care is much more important to us. Standard of care designation for breast cancer is most likely dependent on completion of several large multi-center clinical trials in the U.S. and abroad. Final data from these studies likely will not be presented for two to three years, at the earliest. However, we believe that the surgical community will continue to adopt the ILM application while the standard of care determination is still pending. We also believe that LYMPHOSEEK, the lymphatic targeting agent being developed for us by the University of California, San Diego (UCSD), if it should become commercially available, could improve the adoption of ILM in future years.

We continue to be encouraged by the attention focused on ILM by the medical community at surgical conferences, especially related to investigations into other applications beyond melanoma and breast cancer. We also believe the results from ongoing multinational clinical trials regarding the use of ILM in breast cancer, when announced, will have a positive impact on helping us to penetrate the remaining market for breast cancer and melanoma. We believe the introduction of our laparoscopic probe will ultimately assist surgeons in expanding into areas such as gastric and colon cancers. We also believe the market focus in all major global markets for hand-held gamma detection devices will continue to be among local/community hospitals, which typically lag behind leading research centers and major hospitals in adapting to new technologies. A slower than anticipated adoption rate may negatively impact our sales volumes, and therefore, revenues and net income in 2004.

We have recently received notification from our primary marketing partner, Ethicon Endo-Surgery, Inc. (EES), a Johnson and Johnson company, that they wish to exercise their option to extend the termination date of our distribution agreement with them through the end of 2006. As of December 31, 2003, we had approximately \$1.6 million in committed orders from EES that extend through late April, 2004. We believe that total 2004 purchases of base NEO2000(R) systems by EES should be consistent with their 2003 purchase levels. However, as of March 30, 2004, we are in a backorder position to EES of approximately \$160,000 due to our new contract manufacturer, TriVirix, being in backorder to us. We expect our backorder to EES to be cleared by mid-April. We cannot assure you that EES' product purchases beyond those firmly committed through mid-2004 will indeed occur.

Under the terms of our distribution agreement with EES, the transfer prices we receive on product sales to EES are based on a percentage of their end-customer sales price, subject to a floor transfer price. To date, our products have commanded a price premium in most of the markets in which they are sold, which we believe is due to their superior performance and ease of use. While we

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continue to believe in the technical and user-friendly superiority of our products, competitors continue to innovate and we may lose market share as a result. A loss of market share would likely have a direct negative impact on net income. Although the end-customer average sales price (ASP) may decline due to external market pressures and competition, we do not expect the percentage of ASP shared to change again under the terms of the current distribution agreement. Prices for our gamma detection devices, helped by international exchange rates, have increased over the course of 2003. The price that we received during 2003 was 20% above the floor pricing for base systems, so we believe there is some level of downside pricing risk associated with future sales of our gamma detection devices to EES that we will need to continue to monitor.

We believe the anticipated steady volumes coupled with the reductions in our manufacturing cost that we expect in 2004 will result in improvement in the profitability of our gamma device business line for the year.

### OUR OUTLOOK FOR OUR GAMMA DETECTION RADIOPHARMACEUTICALS

Our outlook for the two potential products in our radiopharmaceutical portfolio has significantly evolved over the last several months. Our RIGS technology, which had been essentially inactive since the failure

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to gain approval following our original license application in 1997, has sparked renewed interest due primarily to the analysis of survival data related to patients who participated in the original Phase III clinical studies that were completed in 1996. The information seems to suggest a potential for a survival differential for patients whose colorectal cancer was evaluated with RIGSCAN(R) CR49. While this renewed interest is by no means an assurance that full-scale development will be invigorated, we have scheduled a meeting for April 15, 2004 to review some of this information with the U.S. Food and Drug Administration (FDA), to determine the appropriate next steps for the development of the product and to outline a possible development timeline. We will provide information after the April 15th meeting as is appropriate in cooperation with the FDA in order to reactivate the currently stalled development plan for RIGSCAN CR49. We have also recently determined that our Biologic License Application (BLA) for RIGSCAN CR49 remains active and that it may be possible for us to provide supplemental clinical data that may address the FDA's patient efficacy questions concerning the product. If the discussions with the FDA on April 15th are positive, Neoprobe expects to conduct a formal survival analysis of all of our evaluable Phase III patients with either primary or metastatic colorectal cancer and to submit the related data to the FDA later this year. If survival data from the original Phase III trials were to be viewed by the FDA as a prospective analysis in response to our original BLA, this may affect our 1998 conclusion that an additional Phase III clinical trial would be necessary in order to gain approval.

During 2003, researchers from the University of California, San Diego (UCSD) continued to work with us in the development of LYMPHOSEEK. LYMPHOSEEK would be the first radiopharmaceutical specifically designed to target lymphatic tissue. Favorable research data from the clinical evaluation of LYMPHOSEEK in breast cancer patients was published in The Annals of Surgical Oncology in June 2003. Evaluation of LYMPHOSEEK in other cancers including gastric and prostate are currently underway. The success of the clinical evaluations of LYMPHOSEEK encouraged Neoprobe to seek regulatory guidance on whether the product was ready to begin pivotal clinical evaluation.

To that end, in November 2003 we met with the Interagency Council on Biomedical Imaging in Oncology (the Interagency Council). The Interagency Council is

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comprised of representatives of the FDA, the National Cancer Institute and Centers for Medicare and Medicaid Services. The Interagency Council is designed to provide guidance to the radiopharmaceutical industry in the development of oncology imaging products. As a result of the meeting, we are preparing a formal submission to the FDA to propose the design of the pivotal evaluation of LYMPHOSEEK as a lymphatic targeting agent. The timing of the submission will be dependent upon the receipt of manufacturing data for LYMPHOSEEK from UCSD and upon the successful transfer of that data to a contract manufacturer for the production of LYMPHOSEEK to support a pivotal clinical study.

### OUR OUTLOOK FOR OUR BLOOD FLOW PRODUCTS

Our efforts concerning the QUANTIX(R) products in 2004 will include some developmental refinements to the Quantix/ND and Quantix/OR systems; however the primary effort will be focused on in the marketing and sales-related activities. Both the Quantix/ND and the Quantix/OR have regulatory clearance to market in the U.S. and EU as well as certain other foreign markets. Currently, we have five (5) distributors covering seventeen (17) countries for the QUANTIX/ND and nine (9) distributors covering over fifteen (15) countries for the QUANTIX/OR. In addition, we have agreements completed or pending with independent cardiovascular sales organizations for the majority of states in the U.S. market for the QUANTIX/OR. Our primary focus is to secure marketing and distribution partners who possess appropriate expertise in marketing medical devices, preferably ultrasound or cardiac care devices, into our primary target markets, the cardiac care and neurosurgical markets.

We anticipate spending a significant amount of time and effort in 2004 to market the Cardiosonix blood flow products to a wider market. We will need to continue to work with our distributors to manage relationships with thought leaders in the cardiac and neurosurgical fields to gain broader exposure to the advantages of our technology. We anticipate placing blood flow systems with industry thought leaders to obtain critical pre-commercialization feedback prior to widespread market launch. The market education process we envision will likely take some time to develop in the manner we desire. In addition, the sales cycle for

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medical devices such as our blood flow products is typically a four to six month cycle. As such, significant end customer sales, if they occur, will likely lag the signing of distribution arrangements.

We expect sales of blood flow products for 2004 to be higher than 2003 although such sales are difficult to gauge in situations where the use of the product is dependent on changes in surgical practice as well as subject to the sales cycles, etc. outlined above. We are also investigating alternative pricing strategies such as per use fees or leasing that may affect the adoption rates for our blood flow measurement devices. As a result, we anticipate that the product development and market support costs we will incur in 2004 will be greater than the revenue we generate from the sales of blood flow devices. We expect to continue to incur losses from our blood flow operations for 2004.

### SUMMARY

The strengthening of our gamma product (device and drug) portfolio coupled with the introduction of the Cardiosonix blood flow products should position us to achieve long-term profitable operating performance. However, overall profitable operational results may be adversely affected to the extent we decide to fund either RIGS or LYMPHOSEEK development activities internally to any significant degree.

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We anticipate generating a net profit from the sale of our gamma detection devices in 2004; however, we expect to show a loss for our blood flow device product line for 2004 due to continued research and development, increased marketing and administrative support costs that are still required to commercialize the product line. Currently, we expect the loss on blood flow products for 2004 to be less than the loss incurred in 2003. However, this expectation is based to a large degree on our anticipation that we will achieve the necessary developmental milestones required to achieve significant commercial sales of our QUANTIX/OR product in a timely manner. The overall operating results for 2004 will be affected by the amount of development for RIGS and LYMPHOSEEK to be funded by development partners. If we are unsuccessful in achieving significant commercial sales of the QUANTIX/OR product in 2004, or if we modify our business plan and decide to carry out RIGS or Lymphoseek development internally, our estimates and our business plan will likely need to be modified.

Depending on the success of our QUANTIX product line and the timing of new product development and regulatory approval cycles, and assuming we do not fund significant RIGS or LYMPHOSEEK development activities internally, we expect to achieve an operating profit on a monthly basis before the end of 2004. However, we cannot assure you that our current or potential new products will be successfully commercialized or that we will achieve significant product revenues. In addition, we cannot assure you that we will achieve or be able to sustain profitability in the future.

### RESULTS OF OPERATIONS

We reported revenues for 2003 of \$6.5 million compared to \$4.9 million in the prior year. The increase in revenue in 2003 versus 2002 is the direct result of an approximately 55% increase in demand from our primary distributor, EES, coupled with a 9% increase in prices received for our gamma detection products. We attribute the increase in demand primarily to EES eliminating their overstock position of base NEO2000 systems that existed throughout most of 2002. Exact market penetration for our products is difficult to gauge, as there are no widely published use statistics on this specific type of device or the application of sentinel lymph node biopsy. However, we believe, based on anecdotal information, that the application of ILM has increased steadily over the past few years, but that the global adoption rate for lymphatic mapping may be slowing pending the outcome of major international trials in breast care.

Our overall gross profit for fiscal year 2003 remained steady with the prior year at 52% of gross revenue. Gross margins on net product sales were 44% of net sales in 2003, as compared to 30% of net product sales in 2002. The increase in gross margins was due primarily to a 9% increase in prices received for our gamma detection products coupled with a 13% decrease in manufacturing cost per gamma detection system for the year. Margins on our blood flow device sales for 2003 were approximately 35%. In addition, we recorded a \$214,000 impairment charge during the third quarter of 2002 related to BLUETIP(R) probe-related inventory that we did not believe had ongoing value to the business. The impairment charge had a 7% negative effect on our gross margins for 2002.

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Results for 2003 also reflect the significant efforts made in the marketing development of Cardiosonix' Angle-independent Doppler Blood Flow (ADBF(TM)) technology; however, the increase in marketing related costs was offset by decreases in our research and development costs for blood flow products. Accordingly, our research and development costs for 2003 decreased to \$1.9 million compared to \$2.3 million in 2002. In addition, consolidated administrative expenses decreased over the prior year with the affect of headcount reductions offsetting the absorption of additional market development

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and other overhead costs associated with Cardiosonix' operations.

Major expense categories as a percentage of net sales decreased from 2002 to 2003 due to the increase in sales of our gamma detection products and initial sales of our blood flow products, coupled with a lower overall cost structure for our gamma business. Research and development expenses, as a percentage of sales, decreased to 34% in 2003 from 69% in 2002 due to the increase in net sales, workforce reductions in our gamma product development and support staff, and decreased incremental development costs associated with the QUANTIX line of blood flow products. Selling, general and administrative expenses, as a percentage of sales, decreased to 56% in 2003 from 97% in 2002 due largely to the increase in net sales coupled with headcount reductions in our gamma product support staff during the third and fourth quarters of 2002. Controlling our costs remains a high priority for us as we endeavor to return to profitability. We believe these major expense categories, as a percentage of sales, will decrease in 2004 as compared to 2003 due to anticipated increases in sales; however, this decrease will depend greatly on our success in achieving commercial sales of our blood flow products and continuing positive trends for our gamma detection products.

YEARS ENDED DECEMBER 31, 2003 AND 2002

Net Sales and Margins. Net sales increased \$2.2 million, or 64%, to \$5.6 million in 2003 from \$3.4 million in 2002. Gross margins on net sales increased to 44% of net sales for 2003 compared to 30% of net sales for 2002. During the third quarter of 2002, we recorded an inventory impairment charge of \$214,000 related to our BLUETIP probe product. This charge adversely affected our gross margins for 2002 by 7 percentage points.

Approximately \$1.9 million of the increase in net sales was the result of increased revenue related to our gamma detection products with the remaining \$245,000 generated from our blood flow products. We had only \$59,000 in revenues from blood flow products during 2002. Of the increased revenue from gamma detection products, approximately 20% was due to increased prices realized on our neo2000 control unit and 14mm probes, with approximately 70% due to increased sales volumes of these products. The remaining 10% was due to various changes in other products and product mix. The price at which we sell our gamma detection products to EES is based on a percentage of the global ASP received by EES on sales of Neoprobe products to end customers, subject to a minimum floor price. The increase in gross margins was primarily due to the higher recorded revenue per gamma detection system combined with lower capitalized internal manufacturing costs as a result of headcount reductions during the third and fourth quarters of 2002 that contributed to lower average costs.

License and Other Revenue. License and other revenue for 2003 and 2002 included \$800,000 from the pro-rata recognition of license fees related to the distribution agreement with EES and \$146,000 and \$520,000, respectively, from the reimbursement by EES of certain product development costs. License and other revenue in 2002 also included \$218,000 from EES' waiver of certain warranty costs due from us in exchange for a release from contractual minimum purchase requirements.

Research and Development Expenses. Research and development expenses decreased \$430,000, or 19%, to \$1.9 million during 2003 from \$2.3 million in 2002. The decrease was primarily due to \$425,000 in lower compensation costs resulting from headcount reductions of gamma product line personnel in the third and fourth quarters of 2002, coupled with decreased use of external design consultants and decreased prototype expenses related to the blood flow product line. 2003 and 2002 also included \$27,000 and \$50,000, respectively, of license fees related to the LYMPHOSEEK targeting agent.



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Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased \$165,000, or 5%, to \$3.1 million during 2003 from \$3.3 million during 2002. The decrease was primarily due to \$232,000 in lower compensation costs resulting from headcount reductions of gamma product line personnel in the third and fourth quarters of 2002, offset by increases in certain overhead costs such as bad debts and insurance and increased selling, general and administrative expenses incurred in the operation and support of Cardiosonix. Selling, general and administrative expenses in 2003 and 2002 included \$30,000 and \$138,000, respectively, in impairment expense related to production equipment and intellectual property that we did not believe had ongoing value to our business. Selling, general and administrative expenses in 2002 also included \$79,000 for the transfer of manufacturing of certain components of the neo2000 gamma detection system to UMM.

Other Income (Expenses). Other income decreased \$217,000 resulting in other expenses of \$188,000 during 2003 compared to other income of \$29,000 during 2002. Other expenses during 2003 consisted primarily of interest expense, amortized discount on our notes payable and interest expense related to the financing of our accounts receivable. Other income during 2002 consisted primarily of interest income. Our interest income decreased because we maintained a lower balance of cash and investments during 2003 as compared to 2002.

### LIQUIDITY AND CAPITAL RESOURCES

Operating Activities. Cash used in operations decreased \$1.2 million to \$1.8 million during 2003 from \$3.0 million during 2002. Working capital increased \$1.4 million to \$2.5 million at December 31, 2003 as compared to \$1.1 million at December 31, 2002. The current ratio increased to 2.6:1 at December 31, 2003 from 1.6:1 at December 31, 2002. The increase in working capital was primarily related to cash received from the sale of common stock.

Cash balances increased to \$1.6 million at December 31, 2003 from \$701,000 at December 31, 2002, primarily due to the cash generated from debt financing arrangements, sales of common stock and the increased net sales experienced during 2003, offset by the requirement to support the operations of Cardiosonix.

Accounts receivable increased to \$1.1 million at December 31, 2003 from \$746,000 at December 31, 2002 due primarily to greater sales in December 2003 than December 2002. During the third quarter of 2003, we entered into an accounts receivable financing facility under which certain of our U.S. accounts receivable were factored at an advance rate of 80% and with recourse to a third party financing company. The factoring arrangement was wound down during the fourth quarter of 2003 and at December 31, 2003 there were no amounts outstanding under this facility. Accounts receivable at December 31, 2003 also included approximately \$350,000 related primarily to our annual transfer price reconciliation with EES. We expect overall receivable levels will continue to fluctuate in 2004 depending on the timing of purchases and payments by EES. However, on average, we expect accounts receivable balances will start to increase commensurate with anticipated increases in sales of blood flow products to our distributors, many of whom are foreign-domiciled entities who typically pay at a slower rate than domestic companies. Such increases, if any, will require the increased use of our cash resources over time.

Inventory levels decreased to \$1.0 million at December 31, 2003 from \$1.2 million at December 31, 2002. Our stock of finished goods of gamma detection products decreased at the end of 2003 more than originally anticipated due to increased demand from EES. In addition, our inventory of gamma device finished goods was lower than normal at the end of 2003 because we are in the process of changing contract manufacturers of our gamma detection devices to a new contract

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manufacturer. Gamma-related raw materials have also continued to decrease compared to prior period due to usage of certain long-lead gamma detection device components that were built up in prior periods to take advantage of quantity price breaks. These decreases were offset by the build-up of raw material and finished goods inventory related to our blood flow products as we continue market launch preparations. We expect inventory levels to increase during the remainder of 2004 as we restore our normal safety stock of inventory of gamma detection equipment and complete finished blood flow devices from our inventory of raw materials.

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**Investing Activities.** Cash used in investing activities decreased to \$109,000 during 2003 from \$315,000 during 2002. During February and March 2002, we invested in \$2.5 million of available-for-sale securities. Capital expenditures during 2003 were primarily purchases of production tools and equipment related to the manufacture of our QUANTIX line of blood flow measurement equipment. Capital expenditures during 2002 were primarily for purchases of production tools and equipment, product development equipment, and technology infrastructure. Capital needs for 2004 are expected to increase over 2003 as we start up blood flow product production at our contract manufacturer.

**Financing Activities.** Financing activities provided \$2.9 million in cash in 2003 versus using \$256,000 during 2002. Proceeds from sales of accounts receivable and subsequent repayments totaled \$914,000 during 2003. Payments of notes payable were \$10,000 higher during 2003 as compared to the same period in 2002 due to the increased cost of financed insurance.

On November 19, 2001, we entered into a common stock purchase agreement with an investment fund, Fusion Capital Fund II, LLC (Fusion) for the issuance and purchase of our common stock. Under the stock purchase agreement, Fusion committed to purchase up to \$10 million of our common stock over a forty-month period that commenced in May 2002. A registration statement registering for resale up to 5 million shares of our common stock became effective on April 15, 2002. Under the terms of the agreement, we can request daily drawdowns, subject to a daily base amount currently set at \$12,500. The number of shares we are to issue to Fusion in return for that money is based on the lower of (a) the closing sale price for our common stock on the day of the draw request or (b) the average of the three lowest closing sales prices for our common stock during a twelve-day period prior to the draw request. However, no shares may be sold to Fusion at lower than a floor price currently set at \$0.30, which may be reduced by us, but in no case below \$0.20 without Fusion's prior consent. Upon execution of the common stock purchase agreement, we issued 449,438 shares of our common stock to Fusion as a commitment fee. During the second half of 2003, we sold Fusion a total of 473,869 shares of common stock and realized net proceeds of \$143,693. We issued Fusion 6,462 shares of common stock for commitment fees due to Fusion related to the sales of our common stock to them during 2003. During the first quarter of 2004 to date, we sold Fusion a total of 2,100,000 shares of common stock and realized proceeds of \$1,271,334. We issued Fusion 57,140 shares of common stock for commitment fees due to Fusion related to the sales of our common stock to them during the first quarter of 2004.

During April 2003, we completed a bridge loan agreement with our President and CEO, David Bupp. Under the terms of the agreement, Mr. Bupp advanced us \$250,000. In consideration for the loan, we issued Mr. Bupp 375,000 warrants, expiring in April 2008, to purchase shares of our common stock at an exercise price of \$0.13 per share. The per share fair value of these warrants was \$0.10 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.9%, volatility of 139% and no expected dividend rate. Interest accrues on the note at the rate of 8.5% per annum, payable monthly, and was due on June 30, 2004. On March 8, 2004,

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we extended the due date of the note due to Mr. Bupp to June 30, 2005. In exchange for extending the due date of the note, we issued Mr. Bupp an additional 375,000 warrants, expiring in March 2009, to purchase our common stock at an exercise price of \$0.50 per share. The per share fair value of these warrants was \$0.46 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.7%, volatility of 152% and no expected dividend rate.

During April 2003, we also completed a convertible bridge loan agreement with Donald E. Garlikov for an additional \$250,000. In consideration for the loan, we issued Mr. Garlikov 500,000 warrants, expiring in April 2008, to purchase shares of our common stock at an exercise price of \$0.13 per share. The per share fair value of these warrants was \$0.10 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.9%, volatility of 139% and no expected dividend rate. Under the terms of the agreement, the note bore interest at 9.5% per annum, payable monthly, and was due on June 30, 2004. During January 2004, Mr. Garlikov converted the entire balance of the note into 1.1 million shares of common stock according to the conversion terms of the agreement. Mr. Garlikov's 500,000 warrants remain outstanding.

During the second and third quarters of 2003, we engaged the services of two investment banking firms to assist us in raising capital, Alberdale Capital, LLC (Alberdale) and Trautman Wasserman & Company, Inc. (Trautman Wasserman). In exchange for Alberdale's services, we agreed to pay them a monthly retainer of \$10,000, half payable in cash and half payable in common stock, and we agreed to pay them additional compensation upon the successful completion of a private placement of our securities. We terminated the agreement with Alberdale effective September 23, 2003, but agreed to issue them a total of 150,943 shares of common stock in payment for one half of their retainer, plus warrants, expiring in

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October 2008, to purchase 78,261 shares of common stock in exchange for their assistance in arranging an accounts receivable financing transaction. The warrants have an exercise price of \$0.28 per share. The per share fair value of these warrants was \$0.33 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.1%, volatility of 150% and no expected dividend rate.

In exchange for the services of Trautman Wasserman, we agreed to pay a retainer of \$10,000, payable in cash and stock, and to pay further compensation on successful completion of a private placement. We agreed to issue Trautman Wasserman a total of 27,199 shares of common stock in payment for one half of their retainer.

During October and November 2003, we executed common stock purchase agreements with third parties introduced to us by a third investment banking firm, Rockwood, Inc., for the purchase of 12,173,914 shares of our common stock at a price of \$0.23 per share for net proceeds of \$2.4 million. In addition, we agreed to issue the purchasers warrants to purchase 6,086,959 shares of common stock at an exercise price of \$0.28 per share and agreed to issue the placement agents warrants to purchase 1,354,348 shares of our common stock on similar terms. All warrants issued in connection with the transaction expire in October 2008. The per share fair value of these warrants was \$0.31 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.2%, volatility of 151% and no expected dividend rate.

Our future liquidity and capital requirements will depend on a number of factors, including our ability to raise additional capital in a timely manner

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through additional investment, expanded market acceptance of our current products, our ability to complete the commercialization of new products such as our blood flow product line, our ability to monetize our investment in non-core technologies, our ability to obtain milestone or development funds from potential development and distribution partners, regulatory actions by the FDA and other international regulatory bodies, and intellectual property protection. Throughout 2002 and the first three quarters of 2003, we made modifications to our operating plan and reduced or delayed planned development and market-support expenditures due primarily to our delayed ability to secure additional sources of financing. We believe our inability to raise financing did not significantly impact our ability to meet the operational milestones we had set for the first half of 2003; however, we believe the effects of the delay in raising financing, coupled with the delay in receiving 510(k) marketing clearance for the QUANTIX/OR until September 2003, hampered our marketing and commercialization efforts for blood flow products during the second half of 2003. Planned resources to support marketing and post-launch development activities were delayed until the completion of the recent financing activities. We had to continually re-assess the timing of our goals and objectives for the second half of 2003 and for calendar year 2004, but believe we now have adequate capital to assure that we can properly support our current business goals and objectives for 2004. Our near-term priorities are the thought leader evaluation and launch of the QUANTIX products in the U.S. and the continued support of such activities ongoing in other markets. In addition, we are considering ways to re-invigorate development of other products in our pipeline such as RIGS. We cannot assure you that we will be able to achieve significant product revenues from our current or potential new products. We also cannot assure you that we will achieve profitability again in 2004.

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### CONTRACTUAL OBLIGATIONS AND COMMERCIAL COMMITMENTS

The following table presents our contractual obligations and commercial commitments as of December 31, 2003.

CONTRACTUAL CASH OBLIGATIONS	PAYMENTS DUE BY PERIOD			
	TOTAL	LESS THAN 1 YEAR	1 - 3 YEARS	4 - YEAR
Capital Leases	\$ 74,854 (1)	\$ 21,436	\$ 36,616	\$ 16,
Operating Leases	283,916 (2)	138,610	145,306	
Unconditional Purchase Obligations	2,147,220 (3)	2,147,220	-	
Long-Term Debt	500,000	250,000 (4)	250,000 (5)	
Total Contractual Cash Obligations	<u>\$3,005,990</u>	<u>\$ 2,557,266</u>	<u>\$ 431,922</u>	<u>\$ 16,</u>

(1) In February 2004, we entered into two (2) three-year capital lease agreements for office equipment. The lease payments total approximately \$10,000 per year.

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- (2) In February 2004, we entered into a six-month operating lease agreement for storage space. The lease payments total approximately \$17,000 in 2004.
- (3) This amount represents purchases under binding purchase orders for which we are required to take delivery of the product under the terms of the underlying supply agreements going out approximately one year.
- (4) In January 2004, Mr. Garlikov converted the entire balance of the note into 1.1 million shares of common stock according to the conversion terms of the agreement.
- (5) In March 2004, the due date of the note to Mr. Bupp was extended to June 30, 2005 under the same terms.

### NEW ACCOUNTING PRONOUNCEMENTS

In June 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143 requires us to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of tangible long-lived assets that result from the acquisition, construction, development, and/or normal use of the assets. We would also be required to record a corresponding asset that is depreciated over the life of the asset. Subsequent to the initial measurement of the asset retirement obligation, the obligation will be adjusted at the end of each period to reflect the passage of time and changes in the estimated future cash flows underlying the obligation. We adopted SFAS No. 143 on January 1, 2003. The adoption of SFAS No. 143 did not have a material effect on our financial statements.

In November 2002, the FASB issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statement Nos. 5, 57 and 107 and a rescission of FASB Interpretation No. 34. This Interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The Interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the Interpretation are applicable to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim and annual periods ending after December 15, 2002. The adoption of Interpretation No. 45 did not have a material effect on our financial statements.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. The Statement requires issuers to classify as liabilities (or assets in some circumstances) three classes of freestanding financial instruments that embody obligations for the issuer. Generally, the Statement is effective for financial instruments entered into or

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modified after May 31, 2003 and is otherwise effective at the beginning of the first interim period beginning after June 15, 2003. We adopted the applicable provisions of the Statement on July 1, 2003. The adoption of SFAS No. 150 did not have a material effect on our financial statements.

### CRITICAL ACCOUNTING POLICIES

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The following accounting policies are considered by us to be critical to our results of operations and financial condition.

**Revenue Recognition Related to Net Sales.** We currently generate revenue primarily from sales of our gamma detection products; however, sales of blood flow products constituted approximately 4% of total revenues for 2003 and are expected to increase in the future. We generally recognize sales revenue related to sales of our products when the products are shipped and the earnings process has been completed. Our customers have no right to return products purchased in the ordinary course of business. However, in cases where product is shipped but the earnings process is not yet completed, revenue is deferred until it has been determined that the earnings process has been completed. We also generate revenue from the service and repair of out-of-warranty products. Fees charged for service and repair on products not covered by an extended service agreement are recognized on completion of the service process when the serviced or repaired product has been returned to the customer. Fees charged for service or repair of products covered by an extended warranty agreement are deferred and recognized as revenue ratably over the life of the extended service agreement. The prices we charge our primary customer, EES, related to sales of products are subject to retroactive annual adjustment based on a fixed percentage of the actual sales prices achieved by EES on sales to end customers made during each fiscal year. To the extent that we can reasonably estimate the end-customer prices received by EES, we record sales to EES based upon these estimates. If we are unable to reasonably estimate end customer sales prices related to certain products sold to EES, we record revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with EES. During 2003, we continued to see improvement in global ASP following a trend that started in the fourth quarter of 2002. As such, management believed it was appropriate to record revenue for 2003 at the estimated sales prices calculated consistently with prior periods per the terms of the distribution agreement.

**Impairment or Disposal of Long-Lived Assets.** We account for long-lived assets in accordance with the provisions of SFAS No. 144. This Statement requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. As of December 31, 2003, the most significant long-lived assets on our balance sheet relate to assets recorded in connection with the acquisition of Cardiosonix and gamma detection device patents related to ILM. The recoverability of these assets is based on the financial projections and models related to the future sales success of Cardiosonix' products and the continuing success of our gamma detection product line. As such, these assets could be subject to significant adjustment should the Cardiosonix technology not be successfully commercialized or the sales amounts in our current projections not be realized.

**Inventory Reserves.** We value our inventory at the lower of cost (first-in, first-out method) or market. Reserves are estimated for excess, slow moving and obsolete inventory as well as inventory with a carrying value in excess of its net realizable value. Write-offs are recorded when product is removed from saleable inventory. We review inventory on hand at least quarterly and record provisions for excess and obsolete inventory based on several factors, including current assessment of future product demand, anticipated release of new products into the market, historical experience and product expiration. Our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of product approvals, variability in product

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launch strategies, product recalls and variation in product utilization all impact the estimates related to excess and obsolete inventory.

Allowance for Doubtful Accounts. We maintain an allowance for doubtful accounts receivable to cover estimated losses resulting from the inability of our customers to make required payments. We determine the adequacy of this allowance by regularly reviewing our accounts receivable aging and evaluating individual customer receivables, considering customer's credit and financial condition, payment history and relevant economic conditions. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances for doubtful accounts may be required.

### OTHER ITEMS AFFECTING FINANCIAL CONDITION

At December 31, 2003, we had U.S. net operating tax loss carryforwards and tax credit carryforwards of approximately \$90.6 million and \$4.3 million, respectively, available to offset or reduce future income tax liability, if any, through 2023. However, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, use of prior tax loss and credit carryforwards may be limited after an ownership change. As a result of ownership changes as defined by Sections 382 and 383,

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which have occurred at various points in our history, we believe utilization of our tax loss carryforwards and tax credit carryforwards may be significantly limited.

### ADDITIONAL INFORMATION

For additional information about our operations, cash flows, liquidity and capital resources, please refer to the information on pages 33 through 37 of this report.

### ITEM 7. FINANCIAL STATEMENTS

Our consolidated financial statements, and the related notes, together with the report of KPMG LLP dated March 29, 2004, are set forth at pages F-1 through F-22 attached hereto.

### ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

### ITEM 8A. CONTROLS AND PROCEDURES.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed to ensure that the information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, possessed, summarized and reported, within the time periods specified in the applicable rules and forms. During the period covered by this Annual Report on Form 10-KSB, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that materially effected, or is reasonably likely to materially effect, our internal control

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over financial reporting.

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### PART III

#### ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

##### DIRECTORS

THE FOLLOWING DIRECTORS' TERMS CONTINUE UNTIL THE 2004 ANNUAL MEETING:

REUVEN AVITAL, age 52, has served as a director of our company since January 2002. Mr. Avital is a partner and general manager of Ma'Aragim Enterprises Ltd., an investment company in Israel, through which he is a member of the board of Neoprobe as well as a number of privately-held Israeli companies, three of them in the medical device field. Mr. Avital was a board member of Cardiosonix, Ltd. from April 2001 through December 31, 2001, when we acquired the company. Previously, Mr. Avital served in the Israeli government in a variety of middle and senior management positions. He is also chairman or board member in several not-for-profit organizations, mainly involved in education for the under-privileged and international peace-building. Mr. Avital has B.A. degrees in The History of the Middle East and International Relations from the Hebrew University of Jerusalem, and a M.P.A. from the Kennedy School of Government at Harvard University.

DAVID C. BUPP, age 54, has served as President and a director of our company since August 1992 and as Chief Executive Officer since February 1998. From August 1992 to May 1993, Mr. Bupp served as our Treasurer. In addition to the foregoing positions, from December 1991 to August 1992, he was Acting President, Executive Vice President, Chief Operating Officer and Treasurer, and from December 1989 to December 1991, he was Vice President, Finance and Chief Financial Officer. From 1982 to December 1989, Mr. Bupp was Senior Vice President, Regional Manager for AmeriTrust Company National Association, a nationally chartered bank holding company, where he was in charge of commercial banking operations throughout Central Ohio. Mr. Bupp has a B.A. degree in Economics from Ohio Wesleyan University. Mr. Bupp completed a course of study at Stonier Graduate School of Banking at Rutgers University.

JULIUS R. KREVANS, M.D., age 79, has served as a director of our company since May 1994 and as Chairman of the Board of Directors of our company since February 1999. Dr. Krevans served as Chancellor of the University of California, San Francisco from July 1982 until May 1993. Prior to his appointment as Chancellor, Dr. Krevans served as a Professor of Medicine and Dean of the School of Medicine at the University of California, San Francisco from 1971 to 1982. Dr. Krevans is a member of the Institute of Medicine, National Academy of Sciences, and led its committee for the National Research Agenda on Aging until 1991. Dr. Krevans has a B.S. degree and a M.D. degree, both from New York University. Dr. Krevans also serves on the Board of Directors and the compensation committee of the Board of Directors of Calypte Biomedical Corporation, a publicly held corporation.

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THE FOLLOWING DIRECTORS' TERMS CONTINUE UNTIL THE 2005 ANNUAL MEETING:

NANCY E. KATZ, age 44, has served as a director of our company since January 2001. Ms. Katz is an independent health care business consultant. Ms. Katz served as President, Chief Executive Officer and a director of Calypte until June 2003. Ms. Katz joined Calypte in October 1999 as President, Chief Operating



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Officer and Chief Financial Officer. Prior to joining Calypte, Ms. Katz served as President of Zila Pharm Inc. From 1997 to 1998, Ms. Katz served as Vice President of Sales & Marketing of LifeScan (the diabetes testing division of Johnson & Johnson) and Vice President of U.S. Marketing, directing LifeScan's marketing and customer call center departments from 1995 to 1997. During her seven-year career at Schering-Plough Healthcare Products from 1987 to 1994, she held numerous positions including Senior Director & General Manager, Marketing Director for Footcare New Products, and Product Director of OTC New Products. Ms. Katz also held various product management positions at American Home Products from 1981 to 1987. Ms. Katz received her B.A. in Business Administration from the University of South Florida.

FRED B. MILLER, age 64, has served as a director of our company since January 2002. Mr. Miller serves as Chairman of the Audit Committee, and the Board of Directors has determined that he (i) meets the requirements of a "financial expert" as set forth in Section 401(e) of Regulation S-B promulgated by the SEC, and (ii) is independent as independence is defined in NASD Rule 4200(a)(15) and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended. Mr. Miller is the President and Chief Operating Officer of Seicon, Limited, a privately held company that specializes in developing, applying and licensing technology to reduce seismic and mechanically induced vibration. Mr. Miller also serves on the boards of two other privately-held companies. Until his retirement in 1995, Mr. Miller had been with Price Waterhouse LLP since 1962. Mr. Miller is a Certified Public Accountant, a member of the American Institute of Certified Public Accountants (AICPA), a past member of the Council of the AICPA and a member and past president of the Ohio Society of Certified Public Accountants. He also has served on the boards or advisory committees of several universities and not-for-profit organizations. Mr. Miller has a B.S. degree in Accounting from the Ohio State University.

THE FOLLOWING DIRECTOR'S TERM CONTINUES UNTIL THE 2006 ANNUAL MEETING:

J. FRANK WHITLEY, JR., age 61, has served as a director of our company since May 1994. Mr. Whitley was Director of Mergers, Acquisitions and Licensing at The Dow Chemical Company (Dow), a multinational chemical company, from June 1993 until his retirement in June 1997. After joining Dow in 1965, Mr. Whitley served in a variety of marketing, financial, and business management functions. Mr. Whitley has a B.S. degree in Mathematics from Lamar State College of Technology.

### EXECUTIVE OFFICERS

In addition to Mr. Bupp, the following individuals are executive officers of our company and serve in the position(s) indicated below:

NAME ----	AGE ---	POSITION -----
Carl M. Bosch	47	Vice President, Instrument Development
Rodger A. Brown	53	Vice President, Regulatory Affairs and Quality Assurance
Brent L. Larson	40	Vice President, Finance; Chief Financial Officer; Treasurer and Secretary
Richard N. Linder	52	Vice President, Sales and Marketing

CARL M. BOSCH has served as Vice President, Instrument Development of our company since March 2000. Prior to that, Mr. Bosch served as our Director,

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Instrument Development from May 1998 to March 2000. Before joining our company, Mr. Bosch was employed by GE Medical Systems from 1994 to 1998 where he served as Manager, Nuclear Programs. From 1977 to 1994, Mr. Bosch was employed by GE Aerospace in several engineering and management functions. Mr. Bosch has a B.S. degree in Electrical Engineering from Lehigh University and a M.S. degree in Systems Engineering from the University of Pennsylvania.

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RODGER A. BROWN has served as Vice President, Regulatory Affairs and Quality Assurance of our company since November 2000. From July 1998 through November 2000, Mr. Brown served as our Director, Regulatory Affairs and Quality Assurance. Prior to joining our company, Mr. Brown served as Director of Operations for Biocore Medical Technologies, Inc. from April 1997 to April 1998. From 1981 through 1996, Mr. Brown served as Director, Regulatory Affairs/Quality Assurance for E for M Corporation, a subsidiary of Marquette Electronics, Inc.

BRENT L. LARSON has served as Vice President, Finance and Chief Financial Officer of our company since February 1999. Prior to that, he served as our Vice President, Finance from July 1998 to January 1999 and as Controller from July 1996 to June 1998. Before joining our company, Mr. Larson was employed by Price Waterhouse LLP. Mr. Larson has a B.B.A. degree in Accounting from Iowa State University of Science and Technology and is a Certified Public Accountant.

RICHARD N. LINDER has served as Vice President, Marketing and Sales of our company since November 2003. Before joining our company, Mr. Linder was employed by XLTEK, Ltd. where he served as Vice President of Sales, Worldwide. From 1999 - 2002, Mr. Linder was employed by Digirad Corporation as Eastern Region Sales Director. From 1997 - 1999, Mr. Linder was employed by Chiron Diagnostics/Bayer Diagnostics in various marketing and sales management functions. Mr. Linder was also employed by i-Stat Corporation from 1991 - 1997 as South Central Regional Sales Director and held various sales positions with other medical device companies from 1978 - 1991. Mr. Linder has a B.S. Degree in Education with endorsements in Biology and Chemistry from Memphis State University.

### SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Act of 1934 requires our officers and directors, and greater than 10% stockholders, to file reports of ownership and changes in ownership of our securities with the Securities and Exchange Commission. Copies of the reports are required by SEC regulation to be furnished to us. Based on our review of these reports and written representations from reporting persons, we believe that all reporting persons complied with all filing requirements during the fiscal year ended December 31, 2003, except for one late Form 4 filing for each of Mr. Linder.

### CODE OF CONDUCT AND ETHICS

We have adopted a code of conduct and ethics that applies to our directors, officers and all employees. The code of conduct and ethics will be posted on our website at [www.neoprobe.com](http://www.neoprobe.com) by the date of the Annual Meeting of Shareholders, or shortly thereafter. Until that time, the code of business conduct and ethics may be obtained free of charge by writing to Neoprobe Corporation, Attn: Chief Financial Officer, 425 Metro Place North, Suite 300, Dublin, Ohio 43017.

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### ITEM 10. EXECUTIVE COMPENSATION

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### SUMMARY COMPENSATION TABLE

The following table sets forth certain information concerning the annual and long-term compensation of our Chief Executive Officer and our other three executive officers having annual compensation in excess of \$100,000 during the last fiscal year (the Named Executives) for the last three fiscal years.

NAME AND PRINCIPAL POSITION	YEAR	ANNUAL COMPENSATION		RESTRICTED STOCK AWARDS (\$)
		SALARY	BONUS	
Carl M. Bosch,	2003	\$135,125	\$ -	-
Vice President,	2002	129,375	-	-
Instrument Development	2001	129,375	25,250	-
Rodger A. Brown,	2003	\$125,316	\$ -	-
Vice President, Regulatory Affairs/	2002	105,417	-	-
Quality Assurance	2001	99,875	19,000	-
David C. Bupp,	2003	\$222,167	\$ 32,500	-
President and	2002	297,083	-	-
Chief Executive Officer	2001	310,000	46,500	-
Brent L. Larson,	2003	\$135,125	\$ -	-
Vice President, Finance and	2002	129,375	-	-
Chief Financial Officer	2001	131,250	20,250	-
Dan Manor,	2003	\$145,000	\$ -	-
President and Chief Executive	2002	145,000	-	-
Officer, Cardiosonix Ltd.(d)	2001	-	-	-

- (a) Amounts represent solely matching contribution under the Neoprobe Corporation 401(k) Plan (the Plan), except for 2003 which includes \$2,703 related to the vesting of restricted stock. Eligible employees may make voluntary contributions and we may, but are not obligated to, make matching contributions based on 40 percent of the employee's contribution, up to five percent of the employee's salary. Employee contributions are invested in mutual funds administered by an independent plan administrator. Company contributions, if any, are made in the form of shares of common stock. The Plan is intended to qualify under section 401 of the Internal Revenue Code, which provides that employee and company contributions and income earned on contributions are not taxable to the employee until withdrawn from the Plan, and that we may deduct our contributions when made.
- (b) Amounts represent matching contribution under the Plan, except for 2003, which includes \$27,090 related to the vesting of restricted stock and social luncheon club dues.
- (c) Amounts represent solely matching contribution under the Plan, except for 2003 which includes \$9,070 related to the vesting of restricted stock.
- (d) Mr. Manor began his employment with our company on January 1, 2002, in connection with our acquisition of Cardiosonix Ltd. (formerly Biosonix Ltd.) and ended his employment on December 31, 2003.

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(e) Amounts represent reimbursements for a company car leased for Mr. Manor's use.

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OPTION GRANTS IN LAST FISCAL YEAR

The following table presents certain information concerning stock options granted to the Named Executives under the 2002 Stock Incentive Plan during the 2003 fiscal year.

NAME -----	NUMBER OF SECURITIES UNDERLYING OPTIONS GRANTED (SHARES) -----	INDIVIDUAL GRANTS -----		EXERCISE PRICE PER SHARE -----	EXPIRATION DATE (d) -----
		PERCENT OF TOTAL OPTIONS GRANTED TO EMPLOYEES IN FISCAL YEAR -----			
Carl M. Bosch	40,000 (a)	3.9%		\$ 0.14 (b)	1/15/13
	30,000 (a)	2.9%		\$ 0.13 (c)	2/15/13
Rodger A. Brown	40,000 (a)	3.9%		\$ 0.14 (b)	1/15/13
	30,000 (a)	2.9%		\$ 0.13 (c)	2/15/13
David C. Bupp	100,000 (a)	9.7%		\$ 0.14 (b)	1/15/13
	70,000 (a)	6.8%		\$ 0.13 (c)	2/15/13
Brent L. Larson	40,000 (a)	3.9%		\$ 0.14 (b)	1/15/13
	30,000 (a)	2.9%		\$ 0.13 (c)	2/15/13
Dan Manor	40,000 (a)	3.9%		\$ 0.14 (b)	1/15/13

- (a) Vests as to one-third of these shares on each of the first three anniversaries of the date of grant.
- (b) The per share weighted average fair value of these stock options during 2003 was \$0.12 on the date of grant using the Black-Scholes option pricing model with the following assumptions: an expected life of 4 years, an average risk-free interest rate of 2.7%, volatility of 146% and no expected dividend rate.
- (c) The per share weighted average fair value of these stock options during 2003 was \$0.11 on the date of grant using the Black-Scholes option pricing model with the following assumptions: an expected life of 4 years, an average risk-free interest rate of 2.5%, volatility of 146% and no expected dividend rate.
- (d) The options terminate on the earlier of the expiration date, nine months after death or disability, 90 days after termination of employment without cause or by resignation or immediately upon termination of employment for cause.

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### FISCAL YEAR-END OPTION NUMBERS AND VALUES

The following table sets forth certain information concerning the number and value of unexercised options held by the Named Executives at the end of the last fiscal year (December 31, 2003). There were no stock options exercised by the Named Executives during the fiscal year ended December 31, 2003.

NAME -----	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FISCAL YEAR-END: EXERCISABLE/UNEXERCISABLE -----	VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT FISCAL YEAR-END: EXERCISABLE/UNEXERCISABLE (1) -----
Carl M. Bosch	121,667 / 118,333	\$0 / \$12,200
Rodger A. Brown	116,167 / 118,333	\$0 / \$12,200
David C. Bupp	410,000 / 450,000	\$0 / \$12,200
Brent L. Larson	173,867 / 123,333	\$0 / \$29,600
Dan Manor	16,667 / 33,333	\$0 / \$ 6,800

(1) Represents the total gain which would be realized if all in-the-money options held at year end were exercised, determined by multiplying the number of shares underlying the options by the difference between the per share option exercise price and the per share fair market value at year end of \$0.31. An option is in-the-money if the fair market value of the underlying shares exceeds the exercise price of the option.

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### COMPENSATION OF NON-EMPLOYEE DIRECTORS

During 2003, the Board of Directors of our company received no cash compensation for board participation or meeting attendance. Each non-employee director received options to purchase 20,000 shares of common stock as a part of our annual stock incentive grants. Options granted to directors to purchase common stock vest on an annual basis over a one-to-three year periods and have exercise prices equal to no less than the market price of common stock at the date of grant.

Directors who are also officers or employees of our company do not receive any compensation for their services as directors.

### COMPENSATION OF MR. BUPP

Employment Agreement. David C. Bupp is employed under a thirty-six month employment agreement effective January 1, 2004. The employment agreement provides for an annual base salary of \$271,250.

The Board of Directors will, on an annual basis, review the performance of our company and of Mr. Bupp and will pay a bonus to Mr. Bupp as it deems appropriate, in its discretion. Such review and bonus will be consistent with any bonus plan adopted by the Compensation Committee that covers the executive officers of our company generally. Mr. Bupp was paid a bonus of \$32,500 relating to fiscal year 2003.

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If a change in control occurs with respect to our company and the employment of Mr. Bupp is concurrently or subsequently terminated:

- by our company without cause (cause is defined as any willful breach of a material duty by Mr. Bupp in the course of his employment or willful and continued neglect of his duty as an employee);
- the term of Mr. Bupp's employment agreement expires; or
- Mr. Bupp resigns because his authority, responsibilities or compensation have materially diminished, a material change occurs in his working conditions or we breach the agreement;

then, Mr. Bupp will be paid a severance payment of \$650,000 (less amounts paid as Mr. Bupp's salary and benefits that continue for the remaining term of the agreement if his employment is terminated without cause). If any such termination occurs after the substantial completion of the liquidation of our assets, the severance payment shall be increased by \$81,250.

For purposes of Mr. Bupp's employment agreement, a change in control includes:

- the acquisition, directly or indirectly, by a person (other than our company or an employee benefit plan established by the Board of Directors) of beneficial ownership of 15 percent or more of our securities with voting power in the next meeting of holders of voting securities to elect the directors;
- a majority of the directors elected at any meeting of the holders of our voting securities are persons who were not nominated by our then current Board of Directors or an authorized committee thereof;
- our stockholders approve a merger or consolidation of our company with another person, other than a merger or consolidation in which the holders of our voting securities outstanding immediately before such merger or consolidation continue to hold voting securities in the surviving or resulting corporation (in the same relative proportions to each other as existed before such event) comprising eighty percent (80%) or more of the voting power for all purposes of the surviving or resulting corporation; or
- our stockholders approve a transfer of substantially all of our assets to another person other than a transfer to a transferee, eighty percent (80%) or more of the voting power of which is owned or controlled by us or by the holders of our voting securities outstanding immediately before such transfer in the same relative proportions to each other as existed before such event.

Mr. Bupp will be paid a severance amount of \$406,250 if his employment is terminated at the end of his employment agreement or without cause and his benefits will continue for the longer of twenty-four months or the full term of the agreement.

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shares of our common stock that was originally granted as restricted stock grants on March 22, 2000, April 30, 1999, May 20, 1998 and June 1, 1996, respectively, pursuant to restricted stock purchase agreements of the same dates. The original grants did not allow Mr. Bupp to transfer or sell any of the restricted shares unless and until they vested and contained certain change of control provisions. However, in connection with the February 1, 2003 amendment to Mr. Bupp's previous employment agreement, we vested Mr. Bupp's interest in the shares. We recognized \$27,090 in compensation expense related to the vesting of the restricted stock in 2003 which occurred as a result of the execution of a February 1, 2003 amendment to Mr. Bupp's previous employment agreement.

### COMPENSATION AGREEMENTS WITH OTHER NAMED EXECUTIVES

Carl M. Bosch

Employment Agreement. Carl Bosch is employed under a twelve-month employment agreement effective January 1, 2004. The employment agreement provides for an annual base salary of \$135,000, and the Company has agreed to review Mr. Bosch's salary by July 1, 2004.

The Compensation Committee will, on an annual basis, review the performance of our company and of Mr. Bosch and we will pay a bonus to Mr. Bosch as we deem appropriate, in our discretion. Such review and bonus will be consistent with any bonus plan adopted by the Compensation Committee that covers the executive officers of our company generally. No bonus was paid to Mr. Bosch relating to fiscal year 2003. Mr. Bosch was paid \$26,000 in salary during 2003 that was deferred under the terms of his previous employment agreement.

If a change in control occurs with respect to our company and the employment of Mr. Bosch is concurrently or subsequently terminated:

- without cause (cause is defined as any willful breach of a material duty by Bosch in the course of his employment or willful and continued neglect of his duty as an employee);
- the term of Mr. Bosch's employment agreement expires; or
- Mr. Bosch resigns because his authority, responsibilities or compensation have materially diminished, a material change occurs in his working conditions or we breach the agreement;

then, Mr. Bosch will be paid a severance payment of \$270,000 and will continue his benefits for the longer of twelve months or the remaining term of his employment agreement.

For purposes of Mr. Bosch's employment agreement, a change in control includes:

- the acquisition, directly or indirectly, by a person (other than our company or an employee benefit plan established by the Board of Directors) of beneficial ownership of 30 percent or more of our securities with voting power in the next meeting of holders of voting securities to elect the directors;
- a majority of the directors elected at any meeting of the holders of our voting securities are persons who were not nominated by our then current Board of Directors or an authorized committee thereof;
- our stockholders approve a merger or consolidation of our company with another person, other than a merger or consolidation in which the holders of our voting securities

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outstanding immediately before such merger or consolidation continue to hold voting securities in the surviving or resulting corporation (in the same relative proportions to each other as existed before such event) comprising eighty percent (80%) or more of the voting power for all purposes of the surviving or resulting corporation; or

- our stockholders approve a transfer of substantially all of the assets of our company to another person other than a transfer to a transferee, eighty percent (80%) or more of the voting power of which is owned or controlled by us or by the holders of our voting securities outstanding immediately before such transfer in the same relative proportions to each other as existed before such event.

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Mr. Bosch will be paid a severance amount of \$135,000 if his employment is terminated at the end of his employment agreement or without cause, and his benefits will be continued for up to twelve months.

Restricted Stock Agreement. Mr. Bosch also holds 30,000 shares of our common stock that were originally granted to him as restricted stock on March 22, 2000, pursuant to a restricted stock purchase agreement with our company as of the same date. Under the original terms of the underlying restricted stock purchase agreement, Mr. Bosch could not transfer or sell any of the restricted shares unless and until they vest. However, in connection with the execution of his previous employment agreement that was effective from February 1, 2003 through December 31, 2003 and Mr. Bosch's waiver of amounts previously deferred under an August 1, 2002 amendment to another previous employment agreement, we vested Mr. Bosch's interest in the shares. We recognized \$3,870 in compensation expense related to the vesting of the restricted stock in 2003 concurrent with the execution of Mr. Bosch's previous employment agreement.

Rodger A. Brown

Employment Agreement. Rodger Brown is employed under a twelve-month employment agreement effective January 1, 2004. The employment agreement provides for an annual base salary of \$115,000, and the Company has agreed to review Mr. Brown's salary by July 1, 2004. Mr. Brown was paid \$32,733 in salary during 2003 that was deferred under the terms of his previous employment agreements.

The terms of Mr. Brown's employment agreement are substantially identical to Mr. Bosch's employment agreement except that Mr. Brown would be paid \$172,500 if terminated due to a change of control and \$115,000 if terminated at the end of his employment or without cause.

The Compensation Committee will, on an annual basis, review the performance of our company and of Mr. Brown and we will pay a bonus to Mr. Brown as we deem appropriate, in our discretion. Such review and bonus will be consistent with any bonus plan adopted by the Compensation Committee that covers the executive officers of our company generally. No bonus was paid to Mr. Brown relating to fiscal year 2003.

Brent L. Larson

Employment Agreement. Brent Larson is employed under a twelve-month employment agreement effective January 1, 2004. The employment agreement provides for an annual base salary of \$135,000 and the Company has agreed to review Mr. Larson's salary by July 1, 2004. Mr. Larson was paid \$26,000 in salary during 2003 that was deferred under the terms of his previous employment agreement.



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The terms of Mr. Larson's employment agreement are substantially identical to Mr. Bosch's employment agreement. The Compensation Committee will, on an annual basis, review the performance of our company and of Mr. Larson and we will pay a bonus to Mr. Larson as we deem appropriate, in our discretion. Such review and bonus will be consistent with any bonus plan adopted by the Compensation Committee that covers the executive officers of our company generally. No bonus was paid to Mr. Larson relating to fiscal year 2003.

Restricted Stock Agreement(s). Mr. Larson also holds 40,000, 20,000 and 10,000 shares of our common stock that were originally granted to him as restricted stock granted to him at a price of \$0.001 per share on March 22, 2000, April 30, 1999 and October 23, 1998, respectively, pursuant to restricted stock purchase agreements of the same dates. The terms of Mr. Larson's restricted stock purchase agreement are identical to those contained in Mr. Bosch's restricted stock purchase agreement discussed above regarding vesting, forfeiture and rights of ownership. However, in connection with the execution of his previous employment agreement that was effective from February 1, 2003 through December 31, 2003 and Mr. Larson's waiver of amounts previously deferred under an August 1, 2002 amendment to another previous employment agreement, we vested Mr. Larson's interest in the shares. We recognized \$9,030 in compensation expense related to the vesting of the restricted stock in 2003 concurrent with the execution of Mr. Larson's previous employment agreement.

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Richard N. Linder

Employment Agreement. Richard N. Linder is employed under a fourteen-month employment agreement effective November 1, 2003. The employment agreement provides for an annual base salary of \$165,000. In exchange for entering into his employment agreement, Mr. Linder received 200,000 options to purchase our common stock with an exercise price of \$0.30 per share that vest one third annually on the anniversary of the date of grant. The terms of Mr. Linder's employment agreement are substantially identical to Mr. Bosch's employment agreement except that Mr. Linder would be paid \$165,000 if terminated due to a change of control and \$82,500 if terminated at the end of his employment or without cause.

The Compensation Committee will, on an annual basis, review the performance of our company and of Mr. Linder and we will pay a bonus to Mr. Linder as we deem appropriate, in our discretion. Such review and bonus will be consistent with any bonus plan adopted by the Compensation Committee that covers the executive officers of our company generally. No bonus was paid to Mr. Linder relating to fiscal year 2003.

Dan Manor

Dan Manor was employed by our subsidiary, Cardiosonix Ltd., as its President under a two-year employment agreement effective January 1, 2002. The employment agreement provided for a monthly basic salary of \$12,083 and automatically renewed for one-year increments unless written notice was given ninety days prior to the end of the then term of the agreement. Dr. Manor will also receive one third of 1% of the Net Revenues (as defined in Dr. Manor's employment agreement) from Cardiosonix products for up to five years from the effective date of the agreement. Cardiosonix also provided Dr. Manor with an automobile allowance, and provided certain statutory benefits under the laws of the State of Israel. Neoprobe and Dr. Manor agreed in September 2003 not to renew his employment agreement following the expiration of its initial term on December 31, 2003; however, the royalty provisions of his agreement survive the end of his employment with Cardiosonix and continue through December 31, 2006.

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ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth additional information as of December 31, 2003, concerning shares of our common stock that may be issued upon the exercise of options and other rights under our existing equity compensation plans and arrangements, divided between plans approved by our stockholders and plans or arrangements not submitted to our stockholders for approval. The information includes the number of shares covered by, and the weighted average exercise price of, outstanding options and other rights and the number of shares remaining available for future grants excluding the shares to be issued upon exercise of outstanding options, warrants, and other rights.

	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (a)	WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (b)	NUMBER REMAIN FOR IS EQUITY PLANS SECURIT IN C
	-----	-----	-----
Equity compensation plans approved by security holders	2,931,308	\$0.56	2,
Equity compensation plans not approved by security holders	-	-	--
Total	2,931,308 =====	\$0.56 =====	2, ==

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SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS, DIRECTORS, NOMINEES AND EXECUTIVE OFFICERS AND RELATED STOCKHOLDER MATTERS

The following table sets forth, as of March 15, 2004, certain information with respect to the beneficial ownership of shares of common stock by (i) each person known to us to be the beneficial owner of more than 5 percent of our outstanding shares of common stock, (ii) each director of our company, (iii) each of the Named Executives (see Item 10, Executive Compensation--Summary Compensation Table), and (iv) our directors and executive officers as a group.

BENEFICIAL OWNER -----	NUMBER OF SHARES BENEFICIALLY OWNED (*) -----	PERCENT OF CLASS -----
Reuven Avital	2,808,457 (a)	5.0%
Carl M. Bosch	255,286 (b)	(n)

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Rodger A. Brown	171,168 (c)	(n)
David C. Bupp	1,710,018 (d)	3.1%
Nancy E. Katz	53,334 (e)	(n)
Julius R. Krevans	197,001 (f)	(n)
Brent L. Larson	348,324 (g)	(n)
Richard N. Linder	21,000 (h)	(n)
Fred B. Miller	24,334 (i)	(n)
J. Frank Whitley, Jr.	114,334 (j)	(n)
All directors and officers as a group (9 persons)	5,703,256 (k)	9.6%
Dan Purjes, et al.	4,463,956 (l)	8.0%
Sands Brothers Venture Funds	3,260,870 (m)	5.9%

(\*) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission which generally attribute beneficial ownership of securities to persons who possess sole or shared voting power and/or investment power with respect to those securities. Unless otherwise indicated, voting and investment power are exercised solely by the person named above or shared with members of such person's household.

(\*\*) Percent of class is calculated on the basis of the number of shares outstanding on March 15, 2004, plus the number of shares the person has the right to acquire within 60 days of March 15, 2004.

(a) This amount consists of 2,785,123 shares of our common stock owned by Ma'Aragim Enterprises Ltd., an investment fund under the management and control of Mr. Avital, and 23,334 shares issuable upon exercise of options which are exercisable within 60 days but does not include 61,666 shares issuable upon exercise of options which are not exercisable within 60 days.

(b) This amount includes 176,668 shares issuable upon exercise of options which are exercisable within 60 days and 38,618 shares in Mr. Bosch's account in the 401(k) Plan, but does not include 133,332 shares issuable upon exercise of options which are not exercisable within 60 days. Mr. Bosch is one of three trustees of the 401(k) Plan and may, as such, share investment power over common stock held in such plan. The 401(k) Plan holds an aggregate total of 274,648 shares of common stock. Mr. Bosch disclaims any beneficial ownership of shares held by the 401(k) Plan that are not allocated to his personal account.

(c) This amount includes 176,168 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 133,332 shares issuable upon exercise of options which are not exercisable within 60 days

(d) This amount includes 586,668 shares issuable upon exercise of options which are exercisable within 60 days and 56,850 shares in Mr. Bupp's account in the 401(k) Plan, but it does not include 423,332 shares issuable upon exercise of options which are not exercisable within 60 days. This amount also includes 375,000 warrants held by Mr. Bupp exercisable at \$0.13 and 375,000 warrants to purchase common stock exercisable at \$0.52. Mr. Bupp is one of three trustees of the 401(k) Plan and may, as such, share investment power over common stock held in such plan. The 401(k) Plan holds an aggregate total of 274,648 shares of common stock. Mr. Bupp disclaims any beneficial ownership of shares held by the 401(k) Plan that are not allocated to his personal account.

(e) This amount includes 53,334 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 61,666 shares issuable upon the exercise of options which are not exercisable within 60 days.

(f) This amount includes 195,001 shares issuable upon exercise of options which

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are exercisable within 60 days, but does not include 104,999 shares issuable upon exercise of options which are not exercisable within 60 days.

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- (g) This amount includes 233,868 shares issuable upon exercise of options which are exercisable within 60 days and 22,889 shares in Mr. Larson's account in the 401(k) Plan, but it does not include 133,332 shares issuable upon exercise of options which are not exercisable within 60 days. Mr. Larson is one of three trustees of the 401(k) Plan and may, as such, share investment power over common stock held in such plan. The 401(k) Plan holds an aggregate total of 274,648 shares of common stock. Mr. Larson disclaims any beneficial ownership of shares held by the 401(k) Plan that are not allocated to his personal account.
- (h) This amount includes 21,000 shares acquired by Mr. Linder prior to his employment with the company, but does not include 200,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (i) This amount includes 23,334 shares issuable upon exercise of options which are exercisable within 60 days and 1,000 shares held by Mr. Miller's wife for which he disclaims beneficial ownership, but does not include 101,666 shares issuable upon the exercise of options which are not exercisable within 60 days.
- (j) This amount includes 113,334 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 61,666 shares issuable upon exercise of options which are not exercisable within 60 days.
- (k) This amount includes 1,576,709 shares issuable upon exercise of options which are exercisable within 60 days, 750,000 shares issuable upon the exercise of warrants which are exercisable within 60 days and 134,424 shares held in the 401(k) Plan, but it does not include 1,214,991 shares issuable upon the exercise of options which are not exercisable within 60 days. Certain executive officers of our company are the trustees of the 401(k) Plan and may, as such, share investment power over common stock held in such plan. Each trustee disclaims any beneficial ownership of shares held by the 401(k) Plan that are not allocated to his personal account. The 401(k) Plan holds an aggregate total of 274,648 shares of common stock.
- (l) This amount is based on information provided to us in connection with the purchase of these securities in a private placement and subsequent filing of the registration statement and represents the best information available to us at the time of this filing. This amount includes 434,783 shares owned by MFW Associates (of which Mr. Purjes is Managing Director) and 217,391 shares issuable to MFW Associates on the exercise of warrants that are exercisable within 60 days, 869,565 shares owned by Dan and Edna Purjes and 434,783 shares issuable to Dan and Edna Purjes on the exercise of warrants that are exercisable within 60 days, 217,391 shares owned by Y Securities Management Ltd. (of which Mr. Purjes is Managing Director) and 108,696 shares issuable to Y Securities Management Ltd. on the exercise of warrants that are exercisable within 60 days, 217,391 shares owned by The Purjes Foundation and 108,696 shares issuable to The Purjes Foundation on the exercise of warrants that are exercisable within 60 days, 869,565 shares owned by Dan Purjes IRA and 434,783 shares issuable to Dan Purjes IRA on the exercise of warrants that are exercisable within 60 days, and 550,913 shares issuable upon the exercise of warrants that are exercisable within 60 days. Mr. Purjes disclaims beneficial ownership of shares held by The Purjes Foundation.
- (m) This amount is based on information provided to us in connection with the

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purchase of these securities in a private placement and subsequent filing of the registration statement and represents the best information available to us at the time of this filing. This amount includes 217,391 shares owned by Sands Brothers Venture Capital I, LLC and 108,696 shares issuable to Sands Brothers Venture Capital I, LLC on the exercise of warrants that are exercisable within 60 days, 217,391 shares owned by Sands Brothers Venture Capital II, LLC and 108,696 shares issuable to Sands Brothers Venture Capital II, LLC on the exercise of warrants that are exercisable within 60 days, 1,304,348 shares owned by Sands Brothers Venture Capital III, LLC and 652,174 shares issuable to Sands Brothers Venture Capital III, LLC on the exercise of warrants that are exercisable within 60 days, and 434,783 shares owned by Sands Brothers Venture Capital IV, LLC and 217,391 shares issuable to Sands Brothers Venture Capital IV, LLC on the exercise of warrants that are exercisable within 60 days.

(n) Less than one percent.

### ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

See "Liquidity and Capital Resources" in Part II, Item 6 of this Form 10-KSB for information about our related party transactions.

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### ITEM 13. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

Exhibit Number -----	Exhibit Description -----
2.1	Stock Purchase Agreement, dated as of November 29, 2001, by and among Neoprobe Corporation, Biosonix, Ltd., and the shareholders of Biosonix, Ltd. Named therein (filed as Exhibit 99(b) to the Company's Current Report on Form 8-K dated November 29, 2001, and incorporated herein by reference).
3.1	Amended and Restated Certificate of Incorporation of Neoprobe Corporation (incorporated by reference to Exhibit 3.1 to the Company's September 30, 2001 Form 10-QSB).
3.2	Amended and Restated By-Laws dated July 21, 1993, as amended July 18, 1995 and May 30, 1996 (filed as Exhibit 99.4 to the Company's Current Report on Form 8-K dated June 20, 1996, and incorporated herein by reference).
10.1	Rights Agreement between the Company and Continental Stock Transfer & Trust Company dated as of July 18, 1995 (incorporated by reference to Exhibit 1 to the Registration Statement of Form 8-A, Commission file No. 0-26520).
10.2	Amendment Number 1 to the Rights Agreement between the Company and Continental Stock Transfer & Trust Company dated February 16, 1999 (incorporated by reference to Exhibit 4.4 to the Company's April 1, 1999 Form 10-K).
10.3	Common Stock Purchase Agreement between the Company and Fusion Capital Fund II, LLC dated November 19, 2001

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(incorporated by reference to Exhibit 99(b) of the Company's December 3, 2001 Form 8-K).

- 10.4 Shareholder Agreement, dated as of December 31, 2001, by and among Neoprobe Corporation and the shareholders of Biosonix, Ltd. named therein (incorporated by reference to Exhibit 99(c) to the Company's Current Report on Form 8-K dated November 29, 2001).
- 10.5 Amended and Restated Stock Option and Restricted Stock Purchase Plan dated March 3, 1994 (incorporated by reference to Exhibit 10.2.26 to the Company's December 31, 1993 Form 10-K).
- 10.6 Restricted Stock Purchase Agreement dated June 5, 1996 between the Company and David C. Bupp (incorporated by reference to Exhibit 10.2.35 to the Company's December 31, 1997 Form 10-K).
- 10.7 1996 Stock Incentive Plan dated January 18, 1996 as amended March 13, 1997 (incorporated by reference to Exhibit 10.2.37 to the Company's December 31, 1997 Form 10-K).
- 10.8 Restricted Stock Purchase Agreement between the Company and David C. Bupp dated May 20, 1998 (incorporated by reference to Exhibit 10.2.45 to the Company's June 30, 1998 Form 10-Q).
- 10.9 Restricted Stock Agreement dated October 23, 1998 between the Company and Brent L. Larson (incorporated by reference to Exhibit 10.2.48 to the Company's December 31, 1998 Form 10-K/A).
- 10.10 Restricted Stock Agreement dated April 30, 1999 between the Company and David C. Bupp. This Agreement is one of three substantially identical agreements and is accompanied by a schedule identifying the other agreements omitted and setting forth the material details in which such agreements differ from the one that is filed

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herewith (incorporated by reference to Exhibit 10.2.50 to the Company's June 30, 1999 Form 10-Q).

- 10.11 Restricted Stock Agreement dated March 22, 2000 between the Company and David C. Bupp. This Agreement is one of three substantially identical agreements and is accompanied by a schedule identifying the other agreements omitted and setting forth the material details in which such agreements differ from the one that is filed herewith (incorporated by reference to Exhibit 10.2.54 of the Company's March 31, 2000 Form 10-Q).
- 10.12 Employment Agreement between the Company and David C. Bupp, dated January 1, 2004.\*

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- 10.13 Employment Agreement between the Company and Carl M. Bosch, dated January 1, 2004. This Agreement is one of three substantially identical agreements and is accompanied by a schedule identifying the other agreements omitted and setting forth the material details in which such agreements differ from the one that is filed herewith.\*
- 10.14 Employment Agreement between Cardiosonix Ltd. (formerly Biosonix Ltd.) and Dan Manor, dated January 1, 2002 (incorporated by reference to Exhibit 10.2.61 to the Company's December 31, 2001 Form 10-KSB).
- 10.15 Technology Transfer Agreement dated July 29, 1992 between the Company and The Dow Chemical Corporation (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission), (incorporated by reference to Exhibit 10.10 to the Company's Form S-1 filed October 15, 1992).
- 10.16 Cooperative Research and Development Agreement between the Company and the National Cancer Institute (incorporated by reference to Exhibit 10.3.31 to the Company's September 30, 1995 Form 10-QSB).
- 10.17 License dated May 1, 1996 between the Company and The Dow Chemical Company (incorporated by reference to Exhibit 10.3.45 to the Company's June 30, 1996 Form 10-QSB).
- 10.18 License Agreement dated May 1, 1996 between the Company and The Dow Chemical Company (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission), (incorporated by reference to Exhibit 10.3.46 to the Company's June 30, 1996 Form 10-QSB).
- 10.19 Supply Agreement between the Company and eV Products dated December 8, 1997 (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission), (incorporated by reference to Exhibit 10.4.32 to Amendment 2 to the Company's December 31, 1997 Form 10-K).
- 10.20 Distribution Agreement between the Company and Ethicon Endo-Surgery, Inc. dated October 1, 1999 (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission), (incorporated by reference to Exhibit 10.4.39 to the Company's September 30, 1999 Form 10-Q).
- 10.21 Product Supply Agreement between the Company and UMM Electronics, Inc., dated October 25, 2001 (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission), (incorporated by reference to Exhibit 10.4.49 to the Company's December 31, 2001

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Form 10-KSB).

- 10.22 Product Supply Agreement between the Company and TriVirix International, Inc., dated February 5, 2004 (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission).\*
- 10.23 Senior Secured Note Purchase Agreement dated March 26, 2003 between the Company and David C. Bupp. (Incorporated by reference to Exhibit 99(b) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.24 8.5% Senior Note dated April 2, 2003 between the Company and David C. Bupp, as amended March 8, 2004.\*
- 10.25 Convertible Preferred Note Purchase Agreement dated March 26, 2003 between the Company and Donald E. Garlikov (Incorporated by reference to Exhibit 99(d) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.26 9.5% Convertible Secured Note dated April 2, 2003 between the Company and Donald E. Garlikov (Incorporated by reference to Exhibit 99(e) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.27 Warrant to Purchase Common Stock of Neoprobe Corporation dated April 2, 2003 between the Company and David C. Bupp (Incorporated by reference to Exhibit 99(f) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.28 Warrant to Purchase Common Stock of Neoprobe Corporation dated March 8, 2004 between the Company and David C. Bupp.\*
- 10.29 Warrant to Purchase Common Stock of Neoprobe Corporation dated April 2, 2003 between the Company and Donald E. Garlikov (Incorporated by reference to Exhibit 99(g) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.30 Security Agreement dated April 2, 2003 between the Company, David C. Bupp and Donald E. Garlikov (Incorporated by reference to Exhibit 99(h) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.31 Registration Rights Agreement dated April 2, 2003 between the Company, David C. Bupp and Donald E. Garlikov (Incorporated by reference to Exhibit 99(i) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.32 Stock Purchase Agreement dated October 22, 2003 between the Company and Bridges & Pipes, LLC. (Incorporated by reference to Exhibit 10.32 to the Company's registration statement on Form SB-2 filed December 2, 2003).
- 10.33 Registration Rights Agreement dated October 22, 2003 between the Company and Bridges & Pipes, LLC (Incorporated by reference to Exhibit 10.33 to the Company's registration statement on Form SB-2 filed December 2, 2003).



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- 10.34 Series R Warrant Agreement dated October 22, 2003 between the Company and Bridges & Pipes, LLC (Incorporated by reference to Exhibit 10.34 to the Company's registration statement on Form SB-2 filed December 2, 2003).
- 10.35 Series S Warrant Agreement dated November 21, 2003 between the Company and Alberdale Capital, LLC (Incorporated by reference to Exhibit 10.35 to the Company's registration statement on Form SB-2 filed December 2, 2003).
- 23.1 Consent of KPMG LLP.\*
- 24.1 Powers of Attorney.\*

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- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32.1 Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.\*
- 32.2 Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.\*

\* Filed herewith.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

**AUDIT FEES.** The aggregate fees billed for professional services rendered by KPMG LLP, for the audits of the Company's annual consolidated financial statements for the 2003 fiscal year and the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-QSB for the fiscal year were \$128,900 (including direct engagement expenses). The aggregate fees billed for professional services rendered by KPMG LLP for the audits of the Company's annual consolidated financial statements for the 2002 fiscal year and the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-QSB for the fiscal year were \$110,730 (including direct engagement expenses).

**AUDIT-RELATED FEES.** The aggregate fees billed by KPMG LLP for audit-related services rendered for the Company for the 2003 fiscal year were \$11,500. The aggregate fees billed KPMG LLP for audit-related services rendered for the Company and its subsidiaries for the 2002 fiscal year were \$15,500. Audit-related fees generally include fees in support of the company's filing of registration statements with the SEC and similar matters.

**TAX FEES.** The aggregate fees billed by KPMG LLP for tax-related services rendered for the Company for the 2003 fiscal year were \$6,525. The aggregate fees billed by KPMG LLP for tax-related services rendered for the Company and its subsidiaries for the 2002 fiscal year were \$8,500. The tax-related services

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were all in the nature of tax compliance and tax planning.

ALL OTHER FEES. The aggregate fees billed for services rendered to the Company by KPMG LLP, other than the audit services, audit-related services, and tax services, were \$0 for the 2003 fiscal year and \$0 for the 2002 fiscal year.

PRE-APPROVAL POLICY. The Audit Committee is required to pre-approve all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for the Company by its independent auditor or other registered public accounting firm, subject to the de minimis exceptions for non-audit services described in Section 10A(i)(1)(B) of the Securities Exchange Act of 1934 that are approved by the Audit Committee prior to completion of the audit.

SIGNATURES

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

Dated: March 30, 2004

NEOPROBE CORPORATION  
(the Company)

By: /s/ David C. Bupp

-----  
David C. Bupp, President and  
Chief Executive Officer

SIGNATURE	TITLE	
/s/David C. Bupp ----- David C. Bupp	Director, President and Chief Executive Officer (principal executive officer)	Marco
/s/ Brent L. Larson* ----- Brent L. Larson	Vice President, Finance and Chief Financial Officer (principal financial officer)	Marco
/s/ Reuven Avital* ----- Reuven Avital	Director	Marco
/s/ Nancy E. Katz* ----- Nancy E. Katz	Director	Marco
/s/ Julius R. Krevans* ----- Julius R. Krevans	Chairman, Director	Marco
/s/ Fred B. Miller* ----- Fred B. Miller	Director	Marco
/s/ J. Frank Whitley, Jr.* ----- J. Frank Whitley, Jr.	Director	Marco

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\*By: /s/ David C. Bupp

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David C. Bupp, Attorney-in-fact

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SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

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NEOPROBE CORPORATION

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FORM 10-KSB ANNUAL REPORT

FOR THE FISCAL YEARS ENDED:

DECEMBER 31, 2003 AND 2002

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FINANCIAL STATEMENTS

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NEOPROBE CORPORATION AND SUBSIDIARY

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Audited Consolidated Financial Statements of Neoprobe Corporation

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## INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders  
Neoprobe Corporation:

We have audited the accompanying consolidated balance sheets of Neoprobe Corporation and subsidiary as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Neoprobe Corporation and subsidiary as of December 31, 2003 and 2002, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Columbus, Ohio  
March 29, 2004

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## NEOPROBE CORPORATION AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS

December 31, 2003 and 2002

	2003	2002
	-----	-----
ASSETS		
Current assets:		
Cash and cash equivalents	\$1,588,760	\$ 700,525
Accounts receivable, net	1,107,800	746,107
Inventory	1,008,326	1,191,918
Prepaid expenses and other	346,449	451,537
	-----	-----
Total current assets	4,051,335	3,090,087
	-----	-----

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Property and equipment	2,237,741	2,346,445
Less accumulated depreciation and amortization	1,875,028	1,883,797
	-----	-----
	362,713	462,648
Patents and trademarks	3,156,101	3,129,031
Non-compete agreements	584,516	584,516
Acquired technology	237,271	237,271
	-----	-----
	3,977,888	3,950,818
Less accumulated amortization	1,042,373	584,490
	-----	-----
	2,935,515	3,366,328
Other assets	35,479	160,778
	-----	-----
Total assets	\$7,385,042	\$7,079,841
	=====	=====

CONTINUED

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NEOPROBE CORPORATION AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS, CONTINUED

	2003	2002
	-----	-----
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable to finance companies	\$ 192,272	\$ 17
Capital lease obligations, current	9,731	1
Accrued liabilities	227,306	39
Accounts payable	225,032	43
Deferred revenue, current	886,657	93
	-----	-----
Total current liabilities	1,540,998	1,95
	-----	-----
Note payable to CEO, net of discount	237,298	
Note payable to investor, net of discount	217,504	
Capital lease obligations	24,009	
Deferred revenue	68,930	70
Contingent consideration for acquisition	--	28
Other liabilities	37,358	17
	-----	-----
Total liabilities	2,126,097	3,11
	-----	-----
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$.001 par value; 5,000,000 shares authorized at December 31, 2003 and 2002; none issued and outstanding (500,000 shares designated as Series A, \$.001 par value, at December 31, 2003 and 2002; none outstanding)		--

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Common stock; \$.001 par value; 75,000,000 shares authorized; 51,520,723 shares issued and outstanding at December 31, 2003; 36,502,183 shares issued and outstanding at December 31, 2002	51,521	3
Additional paid-in capital	127,684,555	124,60
Accumulated deficit	(122,477,131)	(120,67
	-----	-----
Total stockholders' equity	5,258,945	3,96
	-----	-----
Total liabilities and stockholders' equity	\$ 7,385,042	\$ 7,07
	=====	=====

See accompanying notes to consolidated financial statements.

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### NEOPROBE CORPORATION AND SUBSIDIARY CONSOLIDATED STATEMENTS OF OPERATIONS

	YEARS ENDED DECEMBER 31,	
	2003	2002
	-----	-----
Revenues:		
Net sales	\$ 5,564,275	\$ 3,382,707
License and other revenue	945,633	1,538,233
	-----	-----
Total revenues	6,509,908	4,920,940
	-----	-----
Cost of goods sold	3,124,978	2,351,169
	-----	-----
Gross profit	3,384,930	2,569,771
	-----	-----
Operating expenses:		
Research and development	1,893,520	2,323,710
Selling, general and administrative	3,102,535	3,267,361
Acquired in-process research and development	--	(28,368)
	-----	-----
Total operating expenses	4,996,055	5,562,703
	-----	-----
Loss from operations	(1,611,125)	(2,992,932)
	-----	-----
Other income (expense):		
Interest income	9,423	74,257
Interest expense	(186,912)	(31,946)
Other	(10,381)	(13,104)
	-----	-----
Total other (expenses) income	(187,870)	29,207
	-----	-----
Net loss	\$ (1,798,995)	\$ (2,963,725)
	=====	=====

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Net loss per common share:			
Basic	\$	(0.04)	\$ (0.08)
Diluted	\$	(0.04)	\$ (0.08)
Weighted average shares outstanding:			
Basic		40,337,679	36,045,196
Diluted		40,337,679	36,045,196

See accompanying notes to consolidated financial statements.

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NEOPROBE CORPORATION AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital
	Shares	Amount	
Balance, December 31, 2001	36,449,067	\$ 36,449	\$ 124,581,800
Issued to 401(k) plan at \$0.46	53,116	53	24,579
Issued warrants as fees to investor relations firm	--	--	14,018
Registration costs paid in connection with stock purchase agreement	--	--	(24,418)
Registration costs paid in connection with acquisition of subsidiary	--	--	5,791
Net loss	--	--	--
Balance, December 31, 2002	36,502,183	36,502	124,601,770
Issued contingent shares related to 2001 acquisition of subsidiary	2,085,826	2,086	283,100
Removed restrictions on stock issued to executives	--	--	39,990
Issued warrants in connection with issuance of notes payable	--	--	112,994
Issued to 401(k) plan at \$0.26	100,327	100	25,852
Issued shares in connection with stock purchase agreement, net of offering costs	480,331	481	143,212
Issued shares and warrants in connection with private placement, net of offering costs	12,173,914	12,174	2,420,742
Issued shares and warrants as fees to investment banking firms	178,142	178	56,895
Net loss	--	--	--
Balance, December 31, 2003	51,520,723	\$ 51,521	\$ 127,684,555

See accompanying notes to consolidated financial statements.

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NEOPROBE CORPORATION AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEARS ENDED DECEMBER 31,	
	2003	2002
	-----	-----
Cash flows from operating activities:		
Net loss	\$ (1,798,995)	\$ (2,963,725)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	246,975	402,878
Amortization of intangible assets	429,360	393,953
Provision for bad debts	49,582	28,751
Net loss on disposal and abandonment of assets	55,235	130,380
Amortization of debt discount and offering costs	81,449	--
Acquired in-process research and development	--	(28,368)
Other	134,332	64,123
Change in operating assets and liabilities:		
Accounts receivable	(411,275)	(216,429)
Inventory	169,135	213,948
Prepaid expenses and other assets	471,958	65,628
Accrued liabilities and other liabilities	(353,186)	(377,512)
Accounts payable	(207,108)	(57,548)
Deferred revenue	(681,897)	(672,356)
	-----	-----
Net cash used in operating activities	(1,814,435)	(3,016,277)
	-----	-----
Cash flows from investing activities:		
Purchases of available-for-sale securities	--	(2,491,361)
Proceeds from sales of available-for-sale securities	--	1,687,305
Proceeds from maturities of available-for-sale securities	--	805,000
Purchases of property and equipment	(75,456)	(263,012)
Proceeds from sales of property and equipment	250	618
Patent and trademark costs	(34,270)	(29,256)
Subsidiary acquisition costs	--	(24,028)
	-----	-----
Net cash used in investing activities	(109,476)	(314,734)
	-----	-----
Cash flows from financing activities:		
Proceeds from issuance of common stock	2,943,797	--
Payment of offering costs	(370,056)	(48,627)
Proceeds from line of credit	--	2,000,000
Payments under line of credit	--	(2,000,000)
Proceeds from notes payable, net of offering costs	458,334	--
Payment of notes payable	(204,983)	(194,024)
Payments under capital leases	(14,946)	(12,914)
	-----	-----
Net cash provided by (used in) financing activities	2,812,146	(255,565)
	-----	-----
Net increase (decrease) in cash and cash equivalents	888,235	(3,586,576)
	-----	-----
Cash and cash equivalents, beginning of year	700,525	4,287,101
	-----	-----
Cash and cash equivalents, end of year	\$ 1,588,760	\$ 700,525



See accompanying notes to consolidated financial statements.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

- a. ORGANIZATION AND NATURE OF OPERATIONS: Neoprobe Corporation (Neoprobe or we), a Delaware corporation, is engaged in the development and commercialization of innovative surgical and diagnostic products that enhance patient care by meeting the critical decision making needs of healthcare professionals. We currently manufacture two lines of medical devices: the first is a line of gamma radiation detection equipment used in the application of intraoperative lymphatic mapping (ILM), and the second is a line of blood flow monitoring devices for a variety of diagnostic and surgical applications.

Our gamma detection device products are marketed throughout most of the world through a distribution arrangement with Ethicon Endo-Surgery, Inc. (EES), a Johnson and Johnson company. For the years ended December 31, 2003 and 2002, 91% of net sales were made to EES. The loss of this customer would have a significant adverse effect on our operating results.

Our blood flow measurement device product line is in the early stages of commercialization. Our activity with this product line was initiated with our acquisition of Cardiosonix Ltd. (Cardiosonix, formerly Biosonix Ltd.), located in Ra'anana, Israel, on December 31, 2001.

We also have developmental and/or intellectual property rights related to two drugs that might be used in connection with gamma detection devices in cancer surgeries. The first, RIGScan(R) CR49, is intended to be used to help surgeons locate cancerous tissue during colorectal cancer surgeries. The second, Lymphoseek(TM), is intended to be used in tracing the spread of certain solid tumor cancers. Both of these drug products are still in development and must be approved by the appropriate regulatory bodies before they can be sold in any markets.

- b. PRINCIPLES OF CONSOLIDATION: Our consolidated financial statements include the accounts of our company and our wholly-owned subsidiary. All significant inter-company accounts were eliminated in consolidation.
- c. FAIR VALUE OF FINANCIAL INSTRUMENTS: The following methods and assumptions were used to estimate the fair value of each class of financial instruments:
- (1) Cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities: The carrying amounts approximate fair value because of the short maturity of these instruments.
  - (2) Notes payable to finance companies: The fair value of our debt is estimated by discounting the future cash flows at rates currently offered to us for similar debt instruments of comparable maturities by banks or finance companies. At December 31, 2003 and 2002, the carrying values of these instruments approximate fair value.

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- (3) Note payable to CEO: The fair value of our debt is presented as the face amount of the note less the unamortized discount related to the warrants to purchase common stock issued in connection with the note. At December 31, 2003, the carrying value of the note approximates fair value.
- (4) Note payable to outside investor: The fair value of our debt is presented as the face amount of the note less the unamortized discounts related to the conversion feature and the warrants to purchase common stock in connection with the note. At December 31, 2003, the carrying value of the note approximates fair value.
- d. CASH AND CASH EQUIVALENTS: There were no cash equivalents at December 31, 2003 or 2002. None of the cash presented in the December 31, 2003 and 2002 balance sheets is pledged or restricted in any way.
- e. INVENTORY: All components of inventory are valued at the lower of cost (first-in, first-out) or market. We adjust inventory to market value when the net realizable value is lower than the carrying cost of the inventory. Market value is determined based on recent sales activity and margins achieved.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

The components of net inventory at December 31, 2003 and 2002 are as follows:

	2003	2002
	-----	-----
Materials and component parts	\$ 747,788	\$ 760,540
Work in process	--	59,888
Finished goods	260,538	371,490
	-----	-----
	\$1,008,326	\$1,191,918
	=====	=====

During 2003, we wrote off \$70,000 of excess and obsolete Quantix(R)-related materials, primarily due to potential design changes. During 2002, we wrote off \$214,000 of BlueTip(R) probe-related inventory that we did not believe had ongoing value to the business.

- f. PROPERTY AND EQUIPMENT: Property and equipment are stated at cost. Property and equipment under capital leases are stated at the present value of minimum lease payments. Depreciation is computed using the straight-line method over the estimated useful lives of the depreciable assets ranging from 2 to 7 years, and includes amortization related to equipment under capital leases. Maintenance and repairs are charged to expense as incurred, while renewals and improvements are capitalized. Property and equipment includes \$80,000 and \$51,000 of equipment under capital leases with accumulated amortization of \$48,000 and \$30,000 at December 31, 2003 and 2002, respectively. During 2003 and 2002, we recorded losses of \$20,000 and \$2,000, respectively, on the disposal of property and equipment. During 2002, we recorded general and administrative expenses of \$71,000 related to the impairment of BlueTip probe production equipment that we did not believe had ongoing value to

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the business.

The major classes of property and equipment are as follows:

	2003	2002
Production machinery and equipment	\$1,050,806	\$ 981,355
Other machinery and equipment, primarily computers and research equipment	599,193	761,698
Furniture and fixtures	358,760	358,155
Leasehold improvements	117,547	121,808
Software	111,435	123,429
	\$2,237,741	\$2,346,445
	=====	=====

- g. **INTANGIBLE ASSETS:** Intangible assets consist primarily of patents and other acquired intangible assets. Intangible assets are stated at cost, less accumulated amortization. Patent costs are amortized using the straight-line method over the estimated useful lives of the patents of 5 to 15 years. Patent application costs are deferred pending the outcome of patent applications. Costs associated with unsuccessful patent applications and abandoned intellectual property are expensed when determined to have no recoverable value. Non-compete agreements and acquired technology are amortized using the straight-line method over their estimated useful lives of four years and seven years, respectively. We evaluate the potential alternative uses of all intangible assets, as well as the recoverability of the carrying values of intangible assets on a recurring basis. (See also Note 10(b) regarding purchase price adjustments made in 2002 affecting intangible assets acquired as a part of our acquisition of Cardiosonix.)

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

The major classes of intangible assets are as follows:

	DECEMBER 31, 2003		
	GROSS CARRYING AMOUNT	ACCUMULATED AMORTIZATION	GROSS CAR AMOUN
Patents and trademarks	\$3,156,101	\$ 678,160	\$ 3,129,
Non-compete agreements	584,516	295,486	584,
Acquired technology	237,271	68,727	237,
	-----	-----	-----
Total	\$3,977,888	\$ 1,042,373	\$ 3,950,
	=====	=====	=====

During 2003 and 2002, we recorded general and administrative expenses of \$458,000 and \$462,000, respectively, of intangible asset amortization expense. Of those amounts, \$30,000 and \$68,000,

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respectively, related to the abandonment of gamma detection patents and patent applications that were deemed no longer recoverable or part of our ongoing business.

The estimated future amortization expenses for the next five fiscal years are as follows:

	ESTIMATED AMORTIZATION EXPENSE -----
For the year ended 12/31/2004	\$ 427,285
For the year ended 12/31/2005	427,285
For the year ended 12/31/2006	282,770
For the year ended 12/31/2007	214,545
For the year ended 12/31/2008	204,002

### h. REVENUE RECOGNITION

- (1) **PRODUCT SALES:** We derive revenues primarily from sales of our medical devices. We generally recognize sales revenue when the products are shipped and the earnings process has been completed. Our customers have no right to return products purchased in the ordinary course of business.

Sales prices on gamma detection products sold to EES are subject to retroactive annual adjustment based on a fixed percentage of the actual sales prices achieved by EES on sales to end customers made during each fiscal year, subject to a minimum (i.e., floor) price. To the extent that we can reasonably estimate the end customer prices received by EES, we record sales to EES based upon these estimates. To the extent that we are not able to reasonably estimate end customer sales prices related to certain products sold to EES, we record revenue related to these product sales at the floor price provided for under our distribution agreement with EES.

We recognize revenue related to the sales of products to be used for demonstration units when products are shipped and the earnings process has been completed. Our distribution agreements do not permit return of demonstration units in the ordinary course of business nor do we have any performance obligations other than normal product warranty obligations. To the extent that the earnings process has not been completed, revenue is deferred. To the extent we enter into multiple-element arrangements, we allocate revenue based on the relative fair value of the elements.

- (2) **EXTENDED WARRANTY REVENUE:** We derive revenues from the sale of extended warranties covering our medical devices over periods of one to four years. We recognize revenue from extended warranty sales on a pro-rata basis over the period covered by the extended warranty. Expenses related to the extended warranty are recorded when incurred.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

- (3) **SERVICE REVENUE:** We derive revenues from the repair and service of

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our medical devices that are in use beyond the term of the original twelve-month warranty and that are not covered by an extended warranty. We recognize revenue from repair and service activities once the activities are complete and the repaired or serviced device has been returned to the customer.

- (4) LICENSE REVENUE: We recognize license revenue in connection with our distribution agreement with EES on a straight-line basis over the five-year initial term of the agreement based on our obligations to provide ongoing support for the intellectual property being licensed such as patent maintenance and regulatory filings. As the license relates to intellectual property held or in-licensed by us, we incur no significant cost associated with the recognition of this revenue.
- i. RESEARCH AND DEVELOPMENT COSTS: All costs related to research and development are expensed as incurred.
- j. INCOME TAXES: Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities, and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.
- k. STOCK OPTION PLANS: At December 31, 2003, we have three stock-based employee compensation plans (See Note 8(a)). We apply the intrinsic value-based method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations, in accounting for our stock options. As such, compensation expense is recorded on the date of grant and amortized over the period of service only if the current market price of the underlying stock exceeds the exercise price. No stock-based employee compensation cost related to options is reflected in net income (loss), as all options granted under those related to options plans had an exercise price equal to the market value of the underlying common stock on the date of grant. However, we did incur \$39,990 of compensation expense related to the vesting of restricted stock.

The following table illustrates the effect on net income (loss) and earnings (loss) per share if compensation cost for our stock-based compensation plans had been determined based on the fair value at the grant dates for awards under those plans consistent with Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation:

	YEARS ENDED DECEMBER 31,	
	2003	2002
Net loss, as reported	\$(1,798,995)	\$(2,963,725)
Add: Total stock-based employee compensation expense included in reported net loss	39,990	-

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Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(241,437)	(279,161)
	-----	-----
Pro forma net loss	\$ (2,000,442)	\$ (3,242,886)
	=====	=====
Loss per common share:		
As reported (basic and diluted)	\$ (0.04)	\$ (0.08)
Pro forma (basic and diluted)	\$ (0.05)	\$ (0.09)

1. EQUITY ISSUED TO NON-EMPLOYEES: We account for equity instruments granted to non-employees in accordance with the provisions of SFAS No. 123 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. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

of the consideration received or the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the earlier of the date on which the counterpart's performance is complete or the date on which it is probable that performance will occur.

- m. USE OF ESTIMATES: The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.
- n. COMPREHENSIVE INCOME (LOSS): We had no accumulated other comprehensive income (loss) activity during the years ended December 31, 2003 and 2002.
- o. IMPAIRMENT OR DISPOSAL OF LONG-LIVED ASSETS: We account for long-lived assets in accordance with the provisions of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This Statement requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.
2. EARNINGS PER SHARE:
- Basic earnings (loss) per share are calculated using the weighted average

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number of common shares outstanding during the periods. Diluted earnings (loss) per share is calculated using the weighted average number of common shares outstanding during the periods, adjusted for the effects of convertible securities, options and warrants, if dilutive.

	YEAR ENDED DECEMBER 31, 2003		YEAR END DECEMBER 31,
	BASIC EARNINGS PER SHARE	DILUTED EARNINGS PER SHARE	BASIC EARNINGS PER SHARE
Outstanding shares	51,520,723	51,520,723	36,502,183
Effect of weighting changes in outstanding shares	(11,053,044)	(11,053,044)	(16,987)
Contingently issuable shares	(130,000)	(130,000)	(440,000)
Adjusted shares	40,337,679	40,337,679	36,045,196

There is no difference in basic and diluted loss per share related to 2003 or 2002. Basic and diluted loss per share for the year ended December 31, 2002 include 2,085,826 common shares that became issuable to Cardiosonix upon satisfaction of a certain developmental milestone event on December 30, 2002 (See Note 10(b)). The net loss per common share for 2003 and 2002 excludes the number of common shares issuable upon exercise of outstanding stock options and warrants into our common stock since such inclusion would be anti-dilutive.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### 3. ACCOUNTS RECEIVABLE AND CONCENTRATIONS OF CREDIT RISK:

Accounts receivable at December 31, 2003 and 2002, net of allowance for doubtful accounts of \$46,000 and \$29,095, respectively, consist of the following:

	2003	2002
Trade	\$1,063,614	\$ 623,213
Other	44,186	122,894
	\$1,107,800	\$ 746,107

At December 31, 2003 and 2002, approximately 85% and 86%, respectively, of net accounts receivable are due from EES. We do not believe we are exposed to significant credit risk related to EES based on the overall financial strength and credit worthiness of the customer and its parent company. We believe that we have adequately addressed other credit risks in estimating the allowance for doubtful accounts.

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We estimate an allowance for doubtful accounts based on a review and assessment of specific accounts receivable and write off accounts when deemed uncollectible. The activity in the allowance for doubtful accounts for the years ended December 31, 2003 and 2002 is as follows:

	2003	2002
	-----	-----
Allowance for doubtful accounts at beginning of year	\$ 29,095	\$ 39,670
Provision for bad debts	49,582	28,751
Write-offs charged against the allowance	(32,677)	(39,326)
	-----	-----
Allowance for doubtful accounts at end of year	\$ 46,000	\$ 29,095
	=====	=====

#### 4. ACCRUED LIABILITIES AND ACCOUNTS PAYABLE:

Accrued liabilities at December 31, 2003 and 2002 consist of the following:

	2003	2002
	-----	-----
Contracted services and other	\$107,843	\$164,634
Compensation	66,463	177,991
Warranty reserve	53,000	35,000
Inventory purchases	--	19,536
	-----	-----
	\$227,306	\$397,161
	=====	=====

Accounts payable at December 31, 2003 and 2002 consist of the following:

	2003	2002
	-----	-----
Trade	\$146,117	\$391,858
Other	78,915	40,282
	-----	-----
	\$225,032	\$432,140
	=====	=====

#### 5. PRODUCT WARRANTY:

We warrant our products against defects in design, materials, and workmanship generally for a period of one year from the date of sale to the end customer. Our accrual for warranty expenses is adjusted periodically to reflect actual experience. EES also reimburses us for a portion of warranty expense incurred based on end customer sales they make during a given fiscal year. Payments charged against the reserve are disclosed net of EES' reimbursement.



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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

The activity in the warranty reserve account for the years ended December 31, 2003 and 2002 is as follows:

	2003	2002
	-----	-----
Warranty reserve, at beginning of year	\$ 35,000	\$ 90,000
Provision for warranty claims and changes in reserve for warranties	18,464	31,043
Payments charged against the reserve	(464)	(86,043)
	-----	-----
Warranty reserve, at end of year	\$ 53,000	\$ 35,000
	=====	=====

#### 6. NOTES PAYABLE:

During April 2003, we completed a bridge loan agreement with our President and CEO, David Bupp. Under the terms of the agreement, Mr. Bupp advanced us \$250,000. In consideration for the loan, we issued a note in the principal amount of \$250,000. The note was secured by general assets of the company, excluding accounts receivable. Interest accrues on the note at 8.5% per annum, payable monthly, and the note was originally due on June 30, 2004. In addition, we issued Mr. Bupp 375,000 warrants to purchase common stock at an exercise price of \$0.13 per share. See Note 16(b).

During April 2003, we also completed a bridge loan agreement with an outside investor for an additional \$250,000. In consideration for the loan, we issued a note in the principal amount of \$250,000. The note was secured by general assets of the company, excluding accounts receivable. The note bore interest at 9.5% per annum, payable monthly, was convertible into common stock and was due on June 30, 2004. Fifty percent of the principal and accrued interest of the note was convertible into common stock at a 15% discount to the closing market price on the date of conversion, subject to a floor conversion price of \$0.10. The remaining 50% of the principal and accrued interest was convertible into common stock based on a 15% discount to the closing market price on the date of conversion, subject to a floor conversion price of \$0.10 and a ceiling conversion price of \$0.20. In addition, we issued the investor 500,000 warrants to purchase common stock at an exercise price of \$0.13 per share. See Note 16(b).

The per share value of the warrants issued to Mr. Bupp and the outside investor was \$0.10 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.9%, volatility of 139% and no expected dividend rate. The total estimated fair values for the warrants issued to Mr. Bupp and the outside investor were \$31,755 and \$40,620, respectively. These amounts were recorded as a discount on the notes and are being amortized over the period of the notes. At December 31, 2003, the unamortized discounts related to Mr. Bupp's note and the note to the outside investor totaled \$12,702 and \$16,248, respectively. The intrinsic value of the conversion feature of the note to the outside investor was estimated at \$40,620 based on the effective conversion price at the date of issuance and was recorded as an additional discount on the note. The additional discount related to the conversion feature is being amortized over the period of the note. At December 31, 2003 the additional unamortized discount related to the

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conversion feature totaled \$16,248.

### 7. INCOME TAXES:

As of December 31, 2003, our net deferred tax assets in the U.S. were approximately \$35.7 million. Approximately \$30.8 million of the deferred tax assets relate principally to net operating loss carryforwards of approximately \$90.6 million available to offset future taxable income, if any, through 2023. An additional \$4.3 million relates to tax credit carryforwards (principally research and development) available to reduce future income tax liability after utilization of tax loss carryforwards, if any, through 2023. The remaining \$596,000 relates to temporary differences between the carrying amount of assets and liabilities and their tax bases. Due to the uncertainty surrounding the realization of these favorable tax attributes in future tax returns, all of the net deferred tax assets have been fully offset by a valuation allowance at December 31, 2003.

As of December 31, 2003, Cardiosonix had net deferred tax assets in Israel of approximately \$1.8 million, primarily related to net operating loss carryforwards of approximately \$3.7 million available to offset future taxable income, if any. Under current Israeli tax law, net operating loss carryforwards do not expire. Due to the uncertainty surrounding the realization of these favorable tax attributes in future tax returns, all of the net deferred tax assets have been fully offset by a valuation allowance at December 31, 2003. Since a valuation allowance was recognized for the deferred tax asset for Cardiosonix' deductible temporary differences and operating loss carryforwards at the acquisition date, the tax benefits for those items that are first recognized (that is, by elimination of the valuation allowance) in financial statements after the acquisition date shall be applied (a) first to reduce to zero other noncurrent intangible assets related to the acquisition and (b) second to reduce income tax expense.

Under Sections 382 and 383 of the Internal Revenue Code (IRC) of 1986, as amended, the utilization of U.S. net operating loss and tax credit carryforwards may be limited under the change in stock ownership rules of the IRC. As a result of ownership changes as defined by Sections 382 and 383, which have occurred at various points in our history, we believe utilization of our net operating loss carryforwards and tax credit carryforwards may be limited under certain circumstances.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

### 8. EQUITY:

a. STOCK OPTIONS: At December 31, 2003, we have three stock-based compensation plans. Under the Amended and Restated Stock Option and Restricted Stock Purchase Plan (the Amended Plan), the 1996 Stock Incentive Plan (the 1996 Plan), and the 2002 Stock Incentive Plan (the 2002 Plan), we may grant incentive stock options, nonqualified stock options, and restricted stock awards to full-time employees, and nonqualified stock options and restricted awards may be granted to our consultants and agents. Total shares authorized under each plan are 2 million shares, 1.5 million shares and 3 million shares, respectively. Under all three plans, the exercise price of each option is greater than or equal to the closing market price of our common stock on the day prior to the date of the grant.

Options granted under the Amended Plan, the 1996 Plan and the 2002 Plan

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generally vest on an annual basis over three years. Outstanding options under the plans, if not exercised, generally expire ten years from their date of grant or 90 days from the date of an optionee's separation from employment with us.

The fair value of each option grant was estimated on the date of the grant using the Black-Scholes option-pricing model with the following assumptions for 2003 and 2002, respectively: average risk-free interest rates of 2.6% and 4.0%; expected average lives of three to four years for each of the years presented; no dividend rate for any year; and volatility of 146% for 2003 and 145% for 2002. The weighted average fair value of options granted in 2003 and 2002 was \$0.16 and \$0.36, respectively.

A summary of the status of stock options under our stock option plans as of December 31, 2003 and 2002, and changes during the years ended on those dates is presented below:

	2003		2002	
	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding at beginning of year	2,317,725	\$ 0.70	1,862,123	\$ 0.
Granted	1,030,000	\$ 0.18	905,000	\$ 0.
Forfeited	(416,417)	\$ 0.41	(449,398)	\$ 0.
Exercised	-	-	-	
Outstanding at end of year	2,931,308	\$ 0.56	2,317,725	\$ 0.

Included in outstanding options as of December 31, 2003, are 100,000 options exercisable at an exercise price of \$2.50 per share that vest on the meeting of certain company achievements.

The following table summarizes information about our stock options outstanding at December 31, 2003:

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING			OPTIONS EXER
	NUMBER OUTSTANDING AS OF DECEMBER 31, 2003	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE AS OF DECEMBER 31, 2003
\$ 0.13 - \$ 0.40	906,667	9 years	\$ 0.19	40,001
\$ 0.41 - \$ 0.50	1,526,668	7 years	\$ 0.44	980,008
\$ 0.60 - \$ 1.50	325,773	6 years	\$ 1.04	314,107
\$ 2.50 - \$ 5.63	172,200	1 year	\$ 2.67	72,200

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2,931,308  
=====

7 years

\$ 0.56

1,406,316  
=====

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

- b. **RESTRICTED STOCK:** During the first quarter of 2003, we vested 310,000 shares of previously restricted stock related to new or amended employment agreements of three of our officers. We recognized \$39,990 of compensation expense related to this transaction in the first quarter of 2003. At December 31, 2003, we have 130,000 restricted shares outstanding, all of which are pending cancellation due to failure to vest under the terms of issuance of these shares. Restricted shares, if any, generally vest on a change of control of our company as defined in the specific grant agreements. As a result, we have not recorded any deferred compensation related to past grants of restricted stock due to the inability to assess the probability of the vesting event.
- c. **STOCK WARRANTS:** At December 31, 2003, there are 8.5 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from \$0.13 to \$5.00 per share with a weighted average exercise price per share of \$0.30. See Note 16 (b), (e) and (f).

The following table summarizes information about our outstanding warrants at December 31, 2003:

	EXERCISE PRICE	NUMBER OF WARRANTS	EXPIRATION DATE
	-----	-----	-----
Series M	\$ 5.00	50,000	February 2004
Series O	\$ 0.75	25,000	October 2005
Series O	\$ 0.75	25,000	October 2006
Series P	\$ 0.30	50,000	June 2005
Series Q	\$ 0.13	875,000	April 2008
Series R	\$ 0.28	6,086,959	October 2008
Series S	\$ 0.28	1,432,609	October 2008
		-----	
	\$ 0.30	8,544,568	
		=====	

- d. **COMMON STOCK RESERVED:** Shares of authorized common stock have been reserved for the exercise of all options and warrants outstanding.
- e. **COMMON STOCK PURCHASE AGREEMENT:** On November 19, 2001, we entered into a common stock purchase agreement with an investment fund, Fusion Capital Fund II, LLC (Fusion) for the issuance and purchase of our common stock. Under the stock purchase agreement, Fusion committed to purchase up to \$10 million of our common stock over a forty-month period that commenced in May 2002. A registration statement registering for resale up to 5 million shares of our common stock became effective on April 15, 2002. Under the terms of the agreement, we can request daily drawdowns, subject to a daily base amount currently set at \$12,500. The number of shares we are to issue to Fusion in return for

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that money will be based on the lower of (a) the closing sale price for our common stock on the day of the draw request or (b) the average of the three lowest closing sales prices for our common stock during a twelve day period prior to the draw request. However, no shares may be sold to Fusion at lower than a floor price currently set at \$0.30, which may be reduced by us, but in no case below \$0.20 without Fusion's prior consent. Upon execution of the common stock purchase agreement in 2001, we issued 449,438 shares of our common stock to Fusion as a partial payment of the commitment fee. During 2003, we sold Fusion a total of 473,869 shares of common stock and realized net proceeds of \$143,693. We issued Fusion 6,462 shares of common stock during 2003 for commitment fees due to Fusion related to the sales of our common stock to them. See Note 16(e).

- f. PRIVATE PLACEMENT: During the second and third quarters of 2003, we engaged the services of two investment banking firms to assist us in raising capital, Alberdale Capital, LLC (Alberdale) and Trautman Wasserman & Company, Inc. (Trautman Wasserman). In exchange for Alberdale's services, we agreed to pay them a monthly retainer of \$10,000, half payable in cash and half payable in common stock, and we agreed to pay them additional compensation upon the successful completion of a private placement of our securities. We terminated the agreement with Alberdale in September 2003, but agreed to issue them a total of 150,943 shares of common stock in payment for one half of their retainer. The fair market value of \$26,000 related to the shares issued to Alberdale was recorded as general and administrative expense in 2003. In addition, Series S warrants to purchase 78,261 shares of common stock were issued in exchange for their assistance in arranging an accounts receivable financing transaction. The warrants have an exercise price of \$0.28 per share. The per share value of these warrants was \$0.33 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.1%, volatility of 150% and no expected dividend rate. We recorded the estimated fair market value of the warrants issued as additional interest expense. In exchange for the services of Trautman Wasserman, we agreed to pay a retainer of \$10,000, payable in cash and common stock, and to pay further compensation on successful completion of a private placement. We agreed to issue Trautman Wasserman a total of 27,199 shares of common stock in payment for one half of their retainer. The fair market value of \$5,000 related to the shares issued to Trautman Wasserman was recorded as general and administrative expense in 2003. The services of Trautman Wasserman were terminated in September 2003.

In November 2003, we completed a \$2.8 million placement of common stock and warrants for net proceeds of \$2.4 million. In the placement, 12,173,914 shares of common stock were issued at \$0.23 per share, and Series R warrants were issued to purchase an additional 6,086,959 shares of common stock at \$0.28 per share. In addition, we paid \$291,000 in cash and issued 1,354,348 Series S warrants to purchase common stock at \$0.28 per share as fees to the placement agents. All warrants issued in connection with the placement expire in October 2008. The per share value of these warrants was \$0.31 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.2%, volatility of 151% and no expected dividend rate. A registration statement registering for resale the common stock and warrants issued in the private placement was declared effective on December 17, 2003. See Note 16(e).

### 9. SHAREHOLDER RIGHTS PLAN:

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During July 1995, our board of directors adopted a shareholder rights plan. Under the plan, one "Right" is to be distributed for each share of common stock held by shareholders on the close of business on August 28, 1995. The Rights are exercisable only if a person and its affiliate commences a tender offer or exchange offer for 15% or more of our common stock, or if there is a public announcement that a person and its affiliate has acquired beneficial ownership of 15% or more of the common stock, and if we do not redeem the Rights during the specified redemption period. Initially, each Right, upon becoming exercisable, would entitle the holder to purchase from us one unit consisting of 1/100th of a share of Series A Junior Participating preferred stock at an exercise price of \$35 (which is subject to adjustment). Once the Rights become exercisable, if any person, including its affiliate, acquires 15% or more of our common stock, each Right other than the Rights held by the acquiring person and its affiliate becomes a right to

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

acquire common stock having a value equal to two times the exercise price of the Right. We are entitled to redeem the Rights for \$0.01 per Right at any time prior to the expiration of the redemption period. The shareholder rights plan and the Rights will expire on August 28, 2005. The board of directors may amend the shareholder rights plan, from time to time, as considered necessary.

#### 10. SEGMENTS AND SUBSIDIARY INFORMATION:

- a. SEGMENTS: We own or have rights to intellectual property involving two primary types of medical device products, including gamma detection instruments currently used primarily in the application of ILM, and blood flow measurement devices.

The information in the following table is derived directly from each segments' internal financial reporting used for corporate management purposes. Selling, general and administrative costs and other income, including amortization, interest and other costs that relate primarily to corporate activity, are not currently allocated to the operating segments for financial reporting purposes.

(\$ AMOUNTS IN THOUSANDS)	GAMMA DETECTION	BLOOD FLOW	UNALLOCATED
<hr style="border-top: 1px dashed black;"/>			
2003			
Net sales:			
United States(1)	\$ 5,284	\$ -	\$ -
International	35	245	-
License and other revenue	946	-	-
Research and development expenses	(668)	(1,226)	-
Selling, general and administrative expenses	-	-	(3,103)
Income (loss) from operations(2)	2,657	(1,165)	(3,103)
Other expenses	-	-	(188)
Total assets, net of depreciation and amortization:			
United States	1,728	146	1,965
Cardiosonix Ltd.	-	3,546	-

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Capital expenditures	13	50	12
2002			
Net sales			
United States(1)	\$ 3,234	\$ -	\$ -
International	90	59	-
License and other revenue	1,538	-	-
Research and development expenses	(974)	(1,350)	-
Selling, general and administrative Expenses	-	-	(3,267)
Acquired in-process research and development	-	28	-
Income (loss) from operations(2)	1,554	(1,280)	(3,267)
Other income	-	-	29
Total assets, net of depreciation and amortization:			
United States	2,010	6	1,221
Cardiosonix Ltd.	-	3,843	-
Capital expenditures	61	119	83

(1) All sales to EES are made in the United States. EES distributes the product globally through its international affiliates.

(2) Income (loss) from operations does not reflect the allocation of selling, general and administrative costs to the operating segments.

b. SUBSIDIARY: On December 31, 2001, we acquired 100 percent of the outstanding common shares of Cardiosonix, an Israeli company, for \$4.5 million. We accounted for the acquisition under SFAS No. 141, Business Combinations, and certain provisions of SFAS No. 142, Goodwill and Other Intangible Assets. The results of Cardiosonix' operations have been included in our consolidated results from the date of acquisition. Cardiosonix is involved in the development and commercialization of blood

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

flow measurement technology. Cardiosonix currently has two products in the early stages of commercialization and another product in development.

The aggregate purchase price included common stock valued at \$4,271,095; payment of vested options of Cardiosonix employees in the amount of \$17,966; and acquisition costs of \$167,348. The value of the 9,714,737 common shares issued on December 31, 2001 was determined based on the average market price of our common shares over the five-day period before and after the terms of the acquisition were agreed to and announced. A contingent payment of 2,085,826 common shares was also due upon the satisfaction of a certain developmental milestone event.

In accordance with SFAS No. 141, we recorded the contingent amount as if it were a liability in the amount of \$453,602 at the date of acquisition. As a result of the decline in the trading price of our common stock during 2002, the contingent payment was re-valued at \$288,053 upon satisfaction of the milestone event on December 30, 2002. The value of the contingent consideration was determined based on the market price of our common shares. The re-valuation of the contingent

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shares and additional acquisition costs of \$24,000 required us to adjust the final purchase price, resulting in the pro-rata adjustment of certain assets acquired in the acquisition as well as the charge recorded related to in-process research and development (IPR&D). As a result of the adjustment, the balances recorded at December 31, 2001 for patents and trademarks, non-compete agreements, acquired technology, IPR&D and property and equipment were decreased by \$84,000, \$19,000, \$8,000, \$28,000 and \$2,000, respectively, as of December 31, 2002.

As a part of the acquisition, we also entered into a royalty agreement with the three founders of Cardiosonix. Under the terms of the royalty agreement, which expires December 31, 2006, we are obligated to pay the founders an aggregate one percent royalty on up to \$120 million in net revenue generated by the sale of Cardiosonix blood flow products through 2006.

### 11. AGREEMENTS:

- a. **SUPPLY AGREEMENTS:** In December 1997, we entered into an exclusive supply agreement with eV Products (eV), a division of II-VI Incorporated, for the supply of certain crystals and associated electronics to be used in the manufacture of our proprietary line of hand-held gamma detection instruments. The original term of the agreement expired on December 31, 2002 and was automatically extended during 2002 through December 31, 2005; however, the agreement is no longer exclusive for the final three years. During 2001, we built up our stock of crystal modules in order to take advantage of significant quantity price breaks. Our stock of crystal modules was consumed during 2003; therefore we resumed purchasing crystal modules in the fourth quarter of 2003. As a result, total purchases under the supply agreement were \$138,000 and \$82,000 for the years ended December 31, 2003 and 2002, respectively. We have issued a purchase order for \$298,000 of crystal modules for delivery of product through September 2004.

In October 2001, we entered into a manufacturing and supply agreement with UMM Electronics, Inc. (UMM), a Leach Technology Group company, for the exclusive manufacture of the neo2000(R) control unit and 14mm probe. During 2003, we terminated our agreement with UMM for the manufacture of the neo2000 control unit and 14mm probe. As a part of the termination, we were required to purchase \$97,000 in residual materials that were not used by UMM, a portion of which will be used in production at a new contract manufacturer. Total purchases under the manufacturing and supply agreement were \$1.5 million and \$1.2 million for the years ended December 31, 2003 and 2002, respectively.

- b. **MARKETING AND DISTRIBUTION AGREEMENTS:** During 1999, we entered into a distribution agreement with EES covering our gamma detection devices used in ILM. The initial five-year term expires December 31, 2004, with options to extend for two successive two-year terms (See Note 16(d)). Under the agreement, we manufacture and sell our current line of ILM products exclusively to EES, who distributes the products globally. EES agreed to purchase minimum quantities of our products over the first three years of the term of the agreement and to reimburse us for certain research and development costs and a portion of our warranty costs. EES satisfied both its minimum purchase and reimbursement



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requirements during 2002. We are obligated to continue certain product maintenance activities and to provide ongoing regulatory support for the products.

EES may terminate the agreement if we fail to supply products for specified periods, commit a material breach of the agreement, suffer a change of control to a competitor of EES, or become insolvent. If termination were due to failure to supply or a material breach by us, EES would have the right to use our intellectual property and regulatory information to manufacture and sell the products exclusively on a global basis for the remaining term of the agreement with no additional financial obligation to us. If termination is due to insolvency or a change of control that does not affect supply of the products, EES has the right to continue to sell the products on an exclusive global basis for a period of six months or require us to repurchase any unsold products in its inventory.

Under the agreement, EES received a non-exclusive worldwide license to our ILM intellectual property to make and sell other products that may be developed using our ILM intellectual property. The term of the license is the same as that of the agreement. EES paid us a non-refundable license fee of \$4 million. We are recognizing the license fee as revenue on a straight-line basis over the five-year initial term of the agreement. If we terminate the agreement as a result of a material breach by EES, they would be required to pay us a royalty on all products developed and sold by EES using our ILM intellectual property. In addition, we are entitled to a royalty on any ILM product commercialized by EES that does not infringe any of our existing intellectual property.

- c. RESEARCH AND DEVELOPMENT AGREEMENTS: Cardiosonix' research and development efforts have been partially financed through grants from the Office of the Chief Scientist of the Israeli Ministry of Industry and Trade (the OCS). In return for the OCS's participation, Cardiosonix is committed to pay royalties to the Israeli Government at a rate of 3% to 5% of the sales if its products, up to 100% of the amount of the grants received (for grants received under programs approved subsequent to January 1, 1999 - 100% plus interest at LIBOR). Cardiosonix is entitled to the grants only upon incurring research and development expenditures. Cardiosonix is not obligated to repay any amount received from the OCS if the research effort is unsuccessful or if no products are sold. There are no future performance obligations related to the grants received from the OCS. However, under certain limited circumstances, the OCS may withdraw its approval of a research program or amend the terms of its approval. Upon withdrawal of approval, the grant recipient may be required to refund the grant, in whole or in part, with or without interest, as the OCS determines. Cardiosonix' total potential obligation for royalties, based on royalty-bearing government participation, was approximately \$775,000 as of December 31, 2003.

During January 2002, we completed a license agreement with the University of California, San Diego (UCSD) for a proprietary compound that we believe could be used as a lymph node locating agent in ILM procedures. The license agreement is effective until the later of the expiration date of the longest-lived underlying patent or January 30, 2023. Under the terms of the license agreement, UCSD has granted us the exclusive rights to make, use, sell, offer for sale and import licensed products as defined in the agreement and to practice the defined licensed methods during the term of the agreement. We may also sublicense the patent rights, subject to the approval of certain

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sublicense terms by UCSD. In consideration for the license rights, we agreed to pay UCSD a license issue fee of \$25,000 and license maintenance fees of \$25,000 per year. We also agreed to pay UCSD milestone payments related to successful regulatory clearance for marketing of the licensed products, a royalty on net sales of licensed products subject to a \$25,000 minimum annual royalty, fifty percent of all sublicense fees and fifty percent of sublicense royalties. We also agreed to reimburse UCSD for all patent-related costs. Total costs related to the UCSD license agreement were \$29,000 and \$54,000 in 2003 and 2002, respectively, and were recorded in research and development expenses.

UCSD has the right to terminate the agreement or change the nature of the agreement to a non-exclusive agreement if it is determined that we have not been diligent in developing and commercializing the covered products, marketing the products within six months of receiving

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

regulatory approval, reasonably filling market demand or obtaining all the necessary government approvals.

- d. **EMPLOYMENT AGREEMENTS:** We maintain employment agreements with five of our officers. The employment agreements contain change in control provisions that would entitle each of the officers to two times their current annual salaries, vest outstanding restricted stock and options to purchase common stock, and continue certain benefits if there is a change in control of our company (as defined) and their employment terminates. Our maximum contingent liability under these agreements in such an event is approximately \$1.7 million. The employment agreements also provide for severance, disability and death benefits. See Note 16(a).

Cardiosonix also maintains employment agreements with three key employees. The employment agreements contain provisions that would entitle the employees to the greater of one year's salary or the amount due under Israeli law if the employee were terminated without cause. The agreements also provide for royalty payments to the employees (See Note 10(b)). The maximum contingent liability under the agreements, excluding the potential royalty, is approximately \$69,000.

#### 12. LEASES:

We lease certain office equipment under capital leases which expire from 2004 to 2008. In December 1996, we entered into an operating lease agreement for office space, which expired in August 2003. In August 2003, we entered into an operating lease agreement for office space, which expires in September 2006. In April 2002, Cardiosonix entered into an operating sublease agreement for office and parking space, expiring in April 2004. In addition, Cardiosonix leases four automobiles under three-year operating leases.

The future minimum lease payments, net of sublease rentals, for the years ending December 31 are as follows:

CAPITAL  
LEASES

OPERATING  
LEASES

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2004	\$ 13,436	\$ 121,732
2005	7,964	86,738
2006	7,964	58,568
2007	7,964	-
2008	7,300	-
	-----	-----
	44,627	\$ 267,039
Less amount representing interest	10,959	=====
	-----	
Present value of net minimum lease payments	33,740	
Less current portion	9,731	
	-----	
Capital lease obligations, excluding current portion	\$ 24,009	
	=====	

Total rental expense, net of sublease rental income of \$82,000 and \$132,000, was \$238,000 and \$213,000 for the years ended December 31, 2003 and 2002, respectively.

13. EMPLOYEE BENEFIT PLAN:

We maintain an employee benefit plan under Section 401(k) of the Internal Revenue Code. The plan allows employees to make contributions and we may, but are not obligated to, match a portion of the employee's contribution with our common stock, up to a defined maximum. We accrued expenses of \$14,000 and \$26,000 during 2003 and 2002, respectively, related to common stock to be subsequently contributed to the plan.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

14. SUPPLEMENTAL DISCLOSURE FOR STATEMENTS OF CASH FLOWS:

We paid interest aggregating \$94,000 and \$32,000 for the years ended December 31, 2003 and 2002, respectively. During 2002, we received a net refund of \$700 related to overpayment of estimated 2001 income taxes.

During 2003, we purchased equipment under a capital lease totaling \$29,000. During 2003 and 2002, we transferred \$14,000 and \$25,000, respectively, in inventory to fixed assets related to the creation of a pool of service loaner equipment. Also during 2003 and 2002, we prepaid \$225,000 and \$205,000, respectively, in insurance through the issuance of notes payable with weighted average interest rates of 6%. The notes issued in 2003 mature in July and August 2004.

15. CONTINGENCIES:

We are subject to legal proceedings and claims that arise in the ordinary course of business. In our opinion, the amount of ultimate liability, if any, with respect to these actions will not materially affect our financial position.

16. SUBSEQUENT EVENTS:

a. EMPLOYMENT AGREEMENTS: Effective January 1, 2004, we entered into new

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employment agreements with our President and CEO and three other executive officers. The new agreements have substantially similar terms to the previous agreements. The maximum contingent liability under these agreements in the event of termination is \$1.5 million. See Note 11(d).

- b. NOTES PAYABLE: On March 8, 2004, the due date of the note to our President and CEO, David Bupp, was extended from June 30, 2004 to June 30, 2005 with the same terms. In exchange for extending the due date of the note, we issued Mr. Bupp an additional 375,000 warrants, expiring in March 2009, to purchase our common stock at an exercise price of \$0.50 per share. The per share value of these warrants was \$0.46 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.7%, volatility of 152% and no expected dividend rate. See Note 6.

During January 2004, the outside investor converted the entire balance of the note into 1.1 million shares of common stock according to the conversion terms of the agreement. The total value of shares issued in conversion of the note was \$378,955 based on the closing market prices for our common stock on the dates of conversion. See Note 6.

- c. AGREEMENTS: In February 2004, we entered into a product supply agreement with TriVirix International (TriVirix) for the manufacture of the neo2000 control unit, 14mm probe, 11mm laparoscopic probe, Quantix/OR control unit and Quantix/ND control unit. The initial term of the agreement expires in January 2007, but may be automatically extended for successive one-year periods. Either party has the right to terminate the agreement at any time upon one hundred eighty (180) days prior written notice, or may terminate the agreement upon a material breach or repeated non-material breaches by the other. We have issued purchase orders for \$1.8 million of neo2000 control units, 14mm probes and Quantix control units for delivery of product through December 2004.
- d. DISTRIBUTION AGREEMENT: In March 2004, we were notified by EES that they were exercising their option to renew their distribution agreement with us covering our gamma detection devices through the end of 2006. See Note 11(b).
- e. COMMON STOCK PURCHASE AGREEMENT: From January 1 through March 29, 2004, we sold Fusion a total of 2,100,000 shares of common stock and realized proceeds of \$1,271,334. We issued Fusion 57,140 shares of common stock during the first quarter of 2004 for commitment fees due to Fusion related to the sale of our common stock to them. See Note 8(e).
- f. WARRANT EXERCISES: During the first quarter of 2004, certain investors exercised a total of 1.6 million warrants to purchase our common stock and we realized proceeds of \$457,000. See Note 8(c).

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### 17. SUPPLEMENTAL INFORMATION (UNAUDITED):

The following summary financial data are derived from our consolidated financial statements that have been audited by our independent public accountants. These data are qualified in their entirety by, and should be read in conjunction with, our Consolidated Financial Statements and Notes

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thereto included herein.

(Amounts in thousands, except per share data)

YEARS ENDED DECEMBER 31,

	2003	2002	2001	2000
Statement of Operations Data:				
Net sales	\$ 5,564	\$ 3,383	\$ 6,764	\$ 8,8
License and other revenue	946	1,538	1,428	1,3
Gross profit	3,385	2,570	3,802	5,2
Research and development expenses	1,894	2,324	948	9
Selling, general and administrative expenses	3,103	3,267	2,321	2,9
Acquired in-process research and development	-	(28)	885	
Losses related to subsidiaries in liquidation	-	-	-	
(Loss) income from operations	(1,611)	(2,993)	(352)	1,3
Other (expenses) income	(188)	29	370	5
Net (loss) income	\$ (1,799)	\$ (2,964)	\$ 15	\$ 1,8
(Loss) income attributable to common stockholders	\$ (1,799)	\$ (2,964)	\$ 15	\$ 1,0
(Loss) Income per common share:				
Basic	\$ (0.04)	\$ (0.08)	\$ 0.00	\$ 0.
Diluted	\$ (0.04)	\$ (0.08)	\$ 0.00	\$ 0.
Shares used in computing (loss) income per common share: (1)				
Basic	40,338	36,045	25,899	25,7
Diluted	40,338	36,045	26,047	26,4

AS OF DECEMBER 31,

	2003	2002	2001	2000
Balance Sheet Data:				
Total assets	\$ 7,385	\$ 7,080	\$ 11,329	\$ 7,
Long-term obligations	585	1,169	1,981	2,
Accumulated deficit	(122,477)	(120,678)	(117,714)	(117,

(1) Basic earnings (loss) per share are calculated using the weighted average number of common shares outstanding during the periods. Diluted earnings (loss) per share is calculated using the weighted average number of common shares outstanding during the periods, adjusted for the effects of convertible securities, options and warrants, if dilutive.

