

Edgar Filing: NEOPROBE CORP - Form 10KSB

NEOPROBE CORP
Form 10KSB
March 31, 2005

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

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, 2004

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

(State or Other Jurisdiction of
Incorporation or Organization)

(I.R.S. Employer
Identification No.)

425 Metro Place North, Suite 300, Dublin, Ohio

43017-1367

(Address of Principal Executive Offices)

(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

(Title of Class)

Rights to Purchase Series A Junior Participating Preferred Stock

(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.

Edgar Filing: NEOPROBE CORP - Form 10KSB

The issuer's revenues for the fiscal year ended December 31, 2004 were \$5,952,640.

The aggregate market value of shares of common stock held by non-affiliates of the registrant on March 15, 2005 was \$25,571,506.

The number of shares of common stock outstanding on March 15, 2005 was 58,586,008.

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

Neoprobe Corporation (Neoprobe, the company or we) is a biomedical company that develops and commercializes innovative biomedical products that enhance patient care and improve patient outcome by meeting the critical intraoperative diagnostic information needs of physicians and therapeutic treatment needs of patients. 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 1998, we devoted substantially all of our efforts and resources to the research and clinical development of radiopharmaceutical and medical device technologies related to the intraoperative diagnosis and treatment of cancers including our proprietary radioimmunoguided surgery (RIGS(R)) technology. At that point, an evaluation of the status of the regulatory pathway for our RIGS products coupled with our limited financial resources caused us to suspend development activities related to our radiopharmaceutical business and to retrench our organization to focus on our medical device business. After achieving profitability in 2000 following this retrenchment, we set out on a strategy to expand our medical device portfolio outside the cancer field. In December 2001, we took a major step in executing this strategy with the acquisition of Biosonix Ltd., a private Israeli company limited by shares, which we subsequently renamed Cardiosonix Ltd. (Cardiosonix).

Cardiosonix is developing and commercializing the Quantix(R) line of blood flow measurement devices for a variety of diagnostic and surgical applications in the cardiac and vascular management arena. The decision to expand beyond our product focus on oncology was based on our belief that the Cardiosonix products would diversify the markets we address. We believe the Cardiosonix product line 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. Our foray into blood flow measurement devices has not been without its disappointments. The version of the Quantix/ORTM product that was originally launched failed to meet initial user expectations. During 2004, we focused significant effort on redesigning certain aspects of the device, primarily the probe and software, and during 2005 have re-launched an enhanced system that we believe will address the blood flow measurement needs of the user.

In addition, although our strategic focus expanded to include cardiac and

Edgar Filing: NEOPROBE CORP - Form 10KSB

vascular blood flow management, we continued to look for other avenues to reinvigorate our radiopharmaceutical development. During 2004, our efforts resulted in a number of positive events that caused us to take steps to re-activate development of our radiopharmaceutical and therapeutic initiatives. As a result, we now have two of our radiopharmaceutical products, Lymphoseek™ and RIGScan(R) CR, on the verge of entering Phase III clinical trials and have recently formed a new subsidiary, CIRA Biosciences, Inc. (CIRA Bio), to evaluate the current market opportunities for our activated cellular therapy (ACT) technology. Our unique virtual business model combines revenue generation from medical devices with the capital infusions we received in 2004 to allow us to fund Lymphoseek development while we look for a development partner to assist us in the final clinical and commercial development for RIGScan CR and to evaluate the commercial opportunities for ACT.

Our Technology

Gamma Detection Devices

Through 2004, 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 U.S. Food and Drug Administration (FDA) and other international regulatory agencies for marketing and commercial distribution throughout most major global markets.

2

Our patented gamma detection device systems consist of hand-held detector probes and a control unit. The critical detection component is a highly radiosensitive crystal contained in the tip of the probe 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 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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.

Hundreds of 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. Our marketing partner continues to see strong sales, especially for use in breast cancer treatment. 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 National Cancer Institute (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 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 an estimate of the total number of operating rooms in medical centers that are capable of performing the types of procedures in which our gamma devices are used, that roughly 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.

3

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 prostate, 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 additional software-based enhancements to the neo2000 platform as well as new 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 goals for our gamma device business for 2005 center around introducing additional improvements to our neo2000 system and working with our marketing partners to further penetrate the breast care market and identify ways to expand the application of ILM to other indications beyond breast cancer and melanoma. We also believe that our development of Lymphoseek could be an integral step in helping expand the application of ILM.

Blood Flow Measurement Devices

Accurate blood flow measurement is essential for a variety of clinical needs, including:

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

Currently, the medical community has no simple, immediate, real-time means to

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 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 line of products that employ a unique and proprietary technology that allows for measurement of blood flow volume, velocity and several other hemodynamic parameters that permit the real-time assessment of conduit hemodynamic status.

The Quantix 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 designed to provide blood flow measurement and cardiac output information to physicians in cardiac/vascular surgery and neurosurgery. The technology also has the potential to be applied in other healthcare settings where measurement of blood flow may be beneficial.

4

Quantix/NDTM 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, real-time manner. Quantix/ND consists of a control unit and an 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 a complete suite of 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 the vascular cross-sectional area. In most competing devices, the angle of insonation of the device to the vessel is also critical to the measurement and often may affect the user's ability to consistently and accurately measure the patient's blood flow. The Quantix/ND device, as well as its predecessor device, the FlowGuard™, has received CE mark regulatory clearance for marketing in the European Union (EU) as well as FDA 510(k) clearance for marketing in the United States.

Edgar Filing: NEOPROBE CORP - Form 10KSB

Quantix/OR 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 insonation 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 can be very beneficial during anastomotic or other bypass graft procedures to determine adequate blood flow. While measurement is advisable whenever a blood vessel is exposed and manipulated 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 "distention" and strong palpations that may mislead the surgeon. Rather than rely on such a subjective clinical practice, which is highly experience-dependent, the Quantix/OR is designed to allow the surgeon to rely on more quantifiable and objective information. 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. As a result, the majority of surgeons generally resort to finger palpation to qualitatively, rather than quantitatively, measure vessel perfusion.

The initial physician and distributor evaluation of the flagship product, the Quantix/OR, during 2004 indicated a number of design deficiencies that needed to be corrected before further commercial distribution of the product was advisable. The development activities for the Quantix/OR over the last year have therefore involved modification of the user interface software functions and a redesign of the Quantix/OR probe ergonomics to enhance system performance, improve ease of measurement and expand physician acceptance of the system. With completion of the initial development activities for Quantix/OR, we submitted a special 510(k) application to FDA for clearance to market the revised Quantix/OR system in the United States and we received this marketing clearance in early February 2005. In addition, revisions to the technical file in Europe have been completed to permit us to begin delivery of the improved Quantix/OR system in Europe as new flexible probes are received from our contract manufacturer.

Our strategy related to Cardiosonix products for 2005 continues to emphasize the three primary objectives we have established for the Quantix product line:

- o to promote and expand the clinical evaluation of the Quantix/ND and Quantix/OR with thought leaders in the neurosurgical, cardiovascular and vascular surgery arenas;
- o to secure and train additional marketing and distribution partners for key global markets for the Quantix/ND and Quantix/OR devices; and

5

- o to achieve commercial sales of Cardiosonix' Quantix products beyond demonstration unit sales that would demonstrate the initial market acceptance of the products.

Edgar Filing: NEOPROBE CORP - Form 10KSB

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

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 developing recurring revenue or "procedural" products that would generate revenue based on each procedure in which they were used. The product we are working on with the most near-term potential in this area involves an exclusive worldwide license agreement with the University of California, San Diego (UCSD) for a proprietary compound we refer to as Lymphoseek. If proven effective and cleared for commercial sale, Lymphoseek would be the first radiopharmaceutical specifically designed and labeled for the targeting of lymphatic tissue.

Neoprobe and UCSD completed the initial pre-clinical evaluations of Lymphoseek in 2001. Since that time, UCSD has initiated four Phase I clinical trials involving Lymphoseek. The status of these trials is listed below:

Indication -----	Number of Patients	Status -----
Breast (peritumoral injection)	24	Completed
Melanoma	24	Completed
Breast (intra-dermal injection, next day surgery)	60	Ongoing
Prostate	60	Ongoing

These Phase I studies have been supported, including being substantially funded through research grants, by a number of organizations such as the Susan G. Komen Breast Cancer Research Foundation, the American Cancer Society (ACS) and the NCI. Research data from these clinical evaluations of Lymphoseek have been presented at recent meetings of the Society of Nuclear Medicine, the Society of Surgical Oncology and the World Sentinel Node Congress.

In November 2003 we met with the Interagency Council on Biomedical Imaging in Oncology (Interagency Council), an organization representing 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. During 2004, we prepared and submitted a draft clinical protocol to FDA for a pivotal trial to support the marketing clearance of Lymphoseek. FDA has accepted our investigational new drug (IND) submission for Lymphoseek. With the establishment of the corporate IND, responsibility for the clinical and commercial development of Lymphoseek has been officially transferred from UCSD to Neoprobe. Neoprobe has therefore assumed clinical responsibility for the development of Lymphoseek from UCSD. FDA has provided guidance that they would prefer to have Lymphoseek evaluated in a multi-center clinical study to confirm the clinical findings observed by the UCSD researchers to be followed by a confirmation Phase III study that would be initiated with the final cGMP material. Neoprobe intends to commence enrollment in this multi-institutional study as soon as the appropriate regulatory and institutional review board clearances are received. The study will be conducted at some of the nation's leading cancer treatment institutions. FDA guidelines also require Neoprobe to complete some additional preclinical activities prior to the initiation of the multi-center trials. Neoprobe has initiated this preclinical work in parallel to its other development activities and intends to submit an IND amendment prior to the initiation of the multi-center studies. 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-specific 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 CR is an intraoperative agent consisting of a radiolabeled murine monoclonal antibody (MAB CC49). The radiolabel used is ¹²⁵I, a 27 - 35 KeV emitting isotope. The MAB used in RIGScan CR is the CC49 MAB developed by the NCI and licensed to Neoprobe by the National Institutes of Health (NIH). The CC49 MAB is 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 CR is the biologic component for the RIGS system to be used in patients with colon or rectal cancer. The RIGS system was conceived to be a diagnostic aid in the intraoperative detection of clinically occult disease. RIGScan CR 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 CR provides additional information outside that provided by standard diagnostic modalities (including surgical exploration) that may aid in patient management. Specifically, RIGScan CR 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, NEO2-13 and NEO2-14, of RIGScan CR in patients with primary and metastatic colorectal cancer, respectively. 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 CR 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 CR assisted the surgeon in the detection of occult tumor. In 1996, Neoprobe submitted applications to the European Agency for the Evaluation of Medicinal Products (EMEA) and FDA for marketing approval of RIGScan CR for the detection of metastatic colorectal cancer.

Edgar Filing: NEOPROBE CORP - Form 10KSB

Clinical study NEO2-14, which was submitted to FDA in the RIGScan CR Biologic License Application (BLA), enrolled 151 colorectal cancer patients with either suspected metastatic primary colorectal disease or recurrent colorectal disease. During 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 summary report for NEO2-13 was submitted under the BLA; however, FDA undertook no formal review of the study.

7

Following review of our applications, we received requests for further information from FDA and from the European Committee for Proprietary Medicinal Products on behalf of the EMEA. Both 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 for patients with metastatic colorectal cancer. In a series of conversations with FDA the product claims were narrowed to the intraoperative detection of hepatic and perihepatic disease in patients with advanced colorectal cancer and patients with recurrent colorectal cancer.

FDA determined during its review of the BLA that the clinical studies of RIGScan CR 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 CR 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. 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 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.

In recent years, we have obtained access to survival analyses of patients treated with RIGScan CR which have been prepared by third parties, indicating that RIGScan CR 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.

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 FDA has held the BLA originally filed with FDA in 1996 open. Based primarily on these pieces of information, we requested a meeting with 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 originally asked by FDA in response to our original BLA. This meeting with FDA took place in April 2004.

The April 2004 meeting with FDA was an important event in the re-activation of the RIGS program. The meeting was very helpful from a number of aspects: we confirmed that the RIGS BLA remains active and open. We believe this will improve both the cost effectiveness and timeliness of future regulatory submissions for RIGScan CR. Additionally, FDA preliminarily confirmed that the BLA may be applicable to the general colorectal population; and not just the recurrent colorectal market as applied for in 1996. Applicability to a general colorectal population could result in a greater market potential for the product than if applicable to just the recurrent population. During the meeting, FDA indicated that it would consider possible diagnostic and prognostic indications for RIGScan CR and that survival data from one of our earlier Phase III studies could be supportive of a prognostic indication. Our initial submission included a proposed clinical trial design with objectives to demonstrate both diagnostic and prognostic/therapeutic endpoints.

8

In October 2004, Neoprobe received a response from FDA that the prognostic/therapeutic trial design appeared to meet their guidelines, but they requested additional information concerning the diagnostic clinical objective. FDA's response to our clinical submission included an invitation for Neoprobe to seek a special protocol assessment (SPA) of its proposed Phase III study. Neoprobe intends to seek a SPA review of the complete Phase III package including the clinical protocol, training materials and data collection forms later this year. In concert with our meetings with FDA, we met with representatives of the European regulatory body, the EMEA, to seek guidance for the RIGScan CR program in Europe. The guidance from the EMEA was consistent with the input from FDA with the additional recommendation that any future clinical studies be conducted with the humanized version of the RIGScan CR antibody. It is possible that the regulatory pathway may continue to evolve as we seek to reach a consensus with the regulatory agencies on the reactivation of the BLA for RIGScan CR.

In addition, the RIGScan CR biologic 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 FDA for their evaluation before approval could be considered. We have initiated 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 radiolabeling capabilities for the CC49 antibody in order to meet the regulatory needs for the RIGScan CR product.

In parallel with our discussions with the regulatory authorities, we have discussed the clinical and regulatory strategy for RIGScan CR with reimbursement consultants who provided us with valuable input regarding the potential target pricing for a RIGScan product. Our consultants have advised us that if we proceed with our original plans to seek an earlier conditional clearance for the potential diagnostic indications for RIGScan CR, followed by clearance for the

Edgar Filing: NEOPROBE CORP - Form 10KSB

prognostic/therapeutic indication we might significantly limit the ultimate potential price for the prognostic/therapeutic product. However, since we have announced that it is our intention to develop RIGScan CR in cooperation with a development partner, we intend to make the decision on which indications to seek clearance for jointly.

We are encouraged by the recent developments regarding RIGS. We believe we would need to obtain additional funding and/or secure 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 and the completion of the survival analysis proposed to FDA at the April 2004 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 five 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 do not know if a partner will be obtained on a timely basis on terms acceptable to us, or at all. We also cannot assure you that FDA or the EMEA will clear our RIGS products for marketing or that any such products will be successfully introduced or achieve market acceptance. See also Risk Factors.

Activated Cellular Therapy

During the late 1990's, through various research collaborations, we performed early stage research on another technology platform, 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.

9

In the course of our research into ACT performed with RIGS, we learned that these lymph node lymphocytes containing helper T-cells could be activated and expanded to treat viral and autoimmune disease afflicted patients as well as oncology patients. We have seen promising efficacy of this technology demonstrated from six Phase I clinical trials covering the oncology, viral and autoimmune applications.

In early 2005, we formed a new subsidiary, CIRA Bio, to explore the development of ACT. Neoprobe owns approximately 90% of the outstanding shares of CIRA Bio with the remaining shares being held by the principals of a private holding company, CIRA LLC. In conjunction with the formation of CIRA Bio, an amended technology license agreement also was executed with The Ohio State University Research Foundation (OSURF) from whom both Neoprobe and CIRA LLC had originally licensed or optioned the various cellular therapy technologies. As a result of the cross-license agreements, CIRA Bio has the development and commercialization rights to three issued U.S. patents that cover the oncology and autoimmune applications of its technology. In addition, CIRA Bio has licenses to several pending patent applications.

CIRA Bio has engaged the Battelle Memorial Institute to complete a technology and manufacturing process assessment of the cellular therapy approach. In addition, a scientific advisory group is being formed to develop a clinical and regulatory approach for the CIRA Bio technology. Following the completion of these assessments and the formation of a commercialization strategy, CIRA Bio intends to raise the necessary capital to move this technology platform forward.

Edgar Filing: NEOPROBE CORP - Form 10KSB

The means by which this funding is obtained will likely dilute Neoprobe's ownership interest in CIRA Bio; however, we believe that moving forward such a promising technology will only yield positive results for the Neoprobe shareholders and the patients who could benefit from these treatments. However, we do not know if we will be successful in obtaining additional funding, on terms acceptable to us, or at all.

In addition, 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 beyond the evaluation work to be performed in 2005. 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 2004 at \$189.8 billion: \$69.4 billion for direct medical costs, \$16.9 billion for indirect morbidity, and \$103.5 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 ACS, are expected to account for 16% and 4%, respectively, of new cancer cases in the U.S. in 2004.

The 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 second leading cause of death from cancer among all women in the U.S. According to the ACS, over 211,000 new cases of invasive breast cancer are expected to be diagnosed and approximately 41,000 women are expected to die from the disease during 2005 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.

10

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 are currently 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 also to 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.

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 cleared to market, or if cleared to market, that it will achieve the prices or sales we have estimated.

The ACS estimates that over 145,000 new incidences of colon and rectum cancers will occur in the U.S. in 2005. Based on an assumed recurrence rate of 40%, this would translate into total potential surgical procedures of over 200,000 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 CR could, depending on the reimbursement allowed for RIGScan CR, be in excess of \$2 billion annually. However, we cannot assure you that RIGScan CR will be cleared to market, or if cleared to market, that it will receive the reimbursement or achieve the level of sales we have currently estimated.

Blood Flow Measurement 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 80 million physician office visits and over 6.8 million outpatient department visits in 2002 with a primary diagnosis of cardiovascular disease. The CDC registered over 6.8 million inpatient cardiovascular procedures in the U.S. during 2002 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 estimates the total cost of cardiovascular diseases and stroke in the United States will exceed \$393.5 billion in 2005. A substantial portion of these expenditures is expected to be for non-invasive image and intravascular examination. We are focused on two distinct markets within the hospital setting for Cardiosonix' products:

- o non-invasive diagnostics (Quantix/ND); and,
- o intraoperative assessment (Quantix/OR).

It is estimated that there are approximately 1 million vascular and cardiovascular procedures performed in the U.S. that could benefit from qualitative blood flow measurement. Based on these estimates, information obtained from industry sources and data published by our competitors and other medical device companies, we estimate the worldwide total of target procedures to be approximately two times the U.S. totals.

11

Based on the above number of procedures, assuming we are able to achieve market prices that are comparable to what our competitors are achieving (estimated at averaging \$20,000 per system or \$130 per procedural use), we believe the worldwide market potential for blood flow measurement products in the niches which our products address 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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).

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. In March 2004 EES exercised 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

We have not established a marketing or distribution channel for either RIGScan CR or Lymphoseek. We anticipate initiating such discussions as we move forward with the clinical development. We have had initial discussions with parties who may be interested in marketing and distribution of these products; however, such discussions to date have been preliminary in nature and have not resulted in any definitive arrangements at this time. We have engaged a third party business development firm to assist us in identifying a potential development and commercialization partner for our RIGS technology; however, at this time, we have not extended the scope of this firm's engagement to include identifying a partner for Lymphoseek as we intend to manage development and at least the initial stages of commercialization internally. 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

Both of our blood flow measurement devices, the Quantix/ND and Quantix/OR have received marketing clearance in the in the U.S. and the EU and certain other global markets. Our goal is to ensure sales and distribution coverage through third parties of substantially all of the U.S. and EU and selective markets in the rest of the world. To that end, we have put in place a master distributor arrangement covering the major markets in the EU and are working with a number of independent sales organizations to ensure coverage of major markets within the U.S. In addition, we have distribution arrangements in place covering major portions of the Pacific Rim and Central and South America.

The initial negative response to the original Quantix/OR system strained many of our distributor relationships; however, we are heartened by the distributor response to the changes and improvements we have made to the Quantix/OR system. Despite the difficulties we have encountered, our underlying belief in the market need for a reliable system to measure blood flow has not been dampened. We continue to believe strongly in the blood flow market and believe the recently completed changes to our Quantix/OR system will lead to the successful launch of a competitive product in early 2005.

We reintroduced the Quantix/OR to the European surgical community at the Germanic Surgical Congress in Hamburg in February 2005 and we expect to introduce the product to the North American surgical community at the American Association of the Thoracic Surgeons (AATS) meeting in San Francisco in early April.

In addition to the development activities on the Quantix/OR, the first multi-center data from the correlation of CBF measurement with accepted clinical events was presented at the International Conference on Xenon CT-CBF and Related CBF Techniques in Bordeaux, France in June 2004. The presentation of the clinical evaluations of the Quantix/ND has set the stage for the broader adoption of the technology in the monitoring of patients with neuro-trauma and other neurology situations

We anticipate spending a significant amount of time and effort through during 2005 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 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. 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 11mm laparoscopic probe involve the manufacture of

Edgar Filing: NEOPROBE CORP - Form 10KSB

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, 11mm laparoscopic probe and the neo2000 control unit at TriVirix. We also purchase certain accessories for our line of gamma detection systems from other qualified manufacturers.

13

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 February 2004, we executed a Product Supply Agreement with TriVirix for the manufacture of the neo2000, 14mm probe and 11mm laparoscopic probe. We have 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 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

In preparation for the commencement of multi-center clinical evaluation of Lymphoseek, Neoprobe evaluated potential drug manufacturing organizations and initiated the transfer of manufacturing protocols developed at UCSD to the selected contract manufacturing organization. Neoprobe has selected Reliable Biopharmaceuticals (Reliable) to produce the chemical compound that is then labeled at hospital or regional commercial radiopharmacies with Tc99m to become Lymphoseek. Reliable has completed an initial production lot of the unlabeled compound that compares favorably to the material produced by UCSD. Reliable has also been recently favorably inspected by FDA and they will be responsible for the manufacturing section development of our NDA for Lymphoseek. At this point, our agreement with Reliable covers only product to be used in the Phase III clinical trial for Lymphoseek. Further commercial supply and distribution agreements have yet to be negotiated with Reliable. We cannot assure you that we will be successful in reaching an agreement with Reliable on terms satisfactory to us or at all.

In preparation for the initiation of the next phase of clinical evaluation of RIGScan CR, we have initiated discussions with potential biologic manufacturers and radiolabeling organizations. We have held discussions with parties who may assist in the manufacturing validation and radiolabeling of the RIGScan product;

Edgar Filing: NEOPROBE CORP - Form 10KSB

however, we have not yet finalized agreements with these entities. We anticipate finalizing these discussions in the near future to accommodate the planned commencement of RIGScan CR clinical trials. We cannot assure you that we will be successful in securing and/or maintaining the necessary biologic, product and/or radiolabeling capabilities. See also Risk Factors.

Blood Flow Measurement Devices

The Quantix blood flow measurement devices distributed to date have been manufactured by our subsidiary, Cardiosonix Ltd., located in Ra'anana Israel. We intend to transfer the manufacture of Cardiosonix' Quantix product line to contract manufacturers in 2005; however, we are currently in the process of finalizing negotiations on this matter with the Office of the Chief Scientist in Israel. See also Risk Factors. 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. We expect assembly of the Quantix control units at TriVirix to start during the first half of 2005. We currently purchase ultrasound transducer modules and probe subassemblies from Vermon S.A. (Vermon) of France under purchase orders. The ultrasound probe assemblies are then completed by Technical Services for Electronics, Inc. (TSE), also under purchase orders. We are in the process of evaluating subcontractors to manufacture the other accessories associated with the Quantix product line.

14

We cannot assure you that we will be able to finalize supply and service agreements with Vermon, TSE 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.

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 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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. We compete with products produced by Care Wise Medical Products Corporation, Pol.Hi.Tech. Srl, Silicon Instruments GmbH and other companies. GE Healthcare has recently entered the gamma detection market through an arrangement with Intra-Medical Imaging LLC. The effects of their entry into the market cannot be predicted at this time.

It is often difficult to glean accurate competitive information within the lymphatic mapping field, primarily because most of our competitors are either subsidiaries or divisions of a large corporation (i.e., Tyco Healthcare) 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; however, we cannot assure you that competitive products will not be developed, be successful in eroding our market share or affect the prices we receive for our gamma detection devices. See also Risk Factors.

15

Gamma Detection Radiopharmaceuticals

We do not believe there are any directly competitive intraoperative diagnostic radiopharmaceuticals with RIGScan CR that would be used intraoperatively in the colorectal cancer application that RIGScan CR 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 CR.

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 colloid compounds in other markets. However, these drugs are being used "off-label" (i.e., they are not specifically

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 tissue 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

- o 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.
- o 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.
- o 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.

16

Indirect Blood Flow Measurement Devices

- o 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 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).
- o Computed Tomography, Magnetic Resonance Imaging and Single Photon Emission

Edgar Filing: NEOPROBE CORP - Form 10KSB

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.

- o 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.
- o 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.
- o 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.
- o Jugular Bulb Saturation measures the efficiency of oxygen use by the brain. It is invasive, and provides global results.
- o 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:

- o Intraoperative applications: Transonic Systems, Inc., Medi-Stim AS (TT), and Carolina Medical, Inc. (EMF).
- o Neurosurgery applications: HADECO, Hayashi Denki Co., Ltd. (Doppler based), DWL Elektronische Systeme GmbH and Nicolet Biomedical (TCD).

17

Patents and Proprietary Rights

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 Doppler blood flow technology in the EU and the U.S. The first of the two patents covering Cardiosonix technology was issued in the U.S. in January 2003 and claims for the second patent have been allowed. Two patents have been filed

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 patent applications are held by UCSD and licensed exclusively to Neoprobe for lymphatic tissue imaging and detection. 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 and the composition of matter patent is being prosecuted in Japan.

We continue 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. The original methodology aspects of our RIGS technology are claimed in the United States in U.S. Patent No. 4,782,840, which expires in August 2005. However, Neoprobe has recently gained access to additional methodology applications related to our RIGS technology that are covered by patents that provide additional patent coverage through 2018, unless extended. In addition to the RIGS methodology patents, composition of matter patents have been issued in the U.S. and EU that cover the antibodies used in clinical studies. The most recent of these patents issued in 2004.

The activated cellular therapy technology of CIRA Bio is the subject of issued patents in the United States to which Neoprobe has license rights. European patent statutes do not permit patent coverage for treatment technologies such as CIRA Bio's. The oncology applications of CIRA Bio's treatment approach are covered by patents with expiration dates of 2018 and 2020, unless extended. The autoimmune applications are covered by an issued patent with an expiration date of 2018, unless extended. The viral applications are the subject of patent applications and other aspects of the CIRA Bio technology that are in the process of being reviewed by the United States patent office.

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

Edgar Filing: NEOPROBE CORP - Form 10KSB

unauthorized use or disclosure of such information.

18

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, 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, 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 the extensive governmental regulatory requirements applicable to our business. To date, we have not received any notifications or warning letters from 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 FDA to clear medical products for commercial release lengthened and the number of marketing clearances decreased. In response to public and congressional concern, 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 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.

Gamma Detection and Blood Flow Measurement Devices

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 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 FDA in December 1986 with modified versions receiving similar clearances in 1992 through 1997. In 1998, 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.

19

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.

Gamma Detection Radiopharmaceuticals (Lymphoseek and RIGScan)

Our radiolabeled targeting agents and biologic products, if developed, would require a regulatory license to market by 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.

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 post-marketing 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 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 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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, 2005, we had 21 full-time employees, including those of our subsidiary, Cardiosonix. We consider our relations with our employees to be good.

20

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. You should carefully consider the following risk factors, together with the other information in this prospectus, 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 \$126 million as of December 31, 2004. Although we were profitable in 2000 and in 2001, we incurred substantial losses in the years prior to that, and in 2002 through 2004. 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.

Our products and product candidates 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 ongoing adoption 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, 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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.

Our radiopharmaceutical product candidates are still in the process of development, and even if we are successful in commercializing them, we cannot assure you that they will obtain significant market acceptance.

21

Clinical trials for our radiopharmaceutical product candidates will be lengthy and expensive and their outcome is uncertain.

Before obtaining regulatory approval for the commercial sale of any product candidates, we must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting clinical trials is a time consuming, expensive and uncertain process and may take years to complete. Our most advanced product candidates, Lymphoseek and RIGScan CR are preparing to enter the Phase III stage of clinical trials. Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. Frequently, drugs that have shown promising results in preclinical or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. At any time during the clinical trials, we, our collaborative partners or FDA might delay or halt any clinical trials for our product candidates for various reasons, including:

- o ineffectiveness of the product candidate;
- o discovery of unacceptable toxicities or side effects;
- o development of disease resistance or other physiological factors;
- o delays in patient enrollment; or
- o other reasons that are internal to the businesses of our potential collaborative partners, which reasons they may not share with us.

The results of the clinical trials may fail to demonstrate the safety or effectiveness of our product candidates to the extent necessary to obtain regulatory approval or such that commercialization of our product candidates is worthwhile. Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates could severely harm our business.

If we fail to obtain collaborative partners, or those we obtain fail to perform their obligations or discontinue clinical trials for particular product candidates, our ability to develop and market potential products could be severely limited.

Our strategy for the development and commercialization of our product candidates depends, in large part, upon the formation of collaborative arrangements. Collaborations may allow us to:

Edgar Filing: NEOPROBE CORP - Form 10KSB

- o generate cash flow and revenue;
- o offset some of the costs associated with our internal research and development, preclinical testing, clinical trials and manufacturing;
- o seek and obtain regulatory approvals faster than we could on our own; and,
- o successfully commercialize existing and future product candidates.

We do not currently have collaborative agreements covering Lymphoseek or RIGScan CR. We cannot assure you that we will be successful in securing collaborative partners, or that we will be able to negotiate acceptable terms for such arrangements. The development, regulatory approval and commercialization of our product candidates will depend substantially on the efforts of collaborative partners, and if we fail to secure or maintain successful collaborative arrangements, or if our partners fail to perform their obligations, our development, regulatory, manufacturing and marketing activities may be delayed, scaled back or suspended.

We rely on third parties for the worldwide marketing and distribution of our gamma detection and blood flow measurement 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. Our blood flow products are marketed and sold in the U.S. and a number of foreign markets through other distribution partners specific to those markets. Further, our Quantix line of blood flow products has only recently been introduced, and we have only limited experience in marketing or selling these devices. 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 products. If this happens, we may not be able to successfully market our products, which would decrease our revenues.

22

Our radiopharmaceutical product candidates are subject to extensive government regulations and we may not be able to obtain necessary regulatory approvals.

We may not receive the regulatory approvals necessary to commercialize our Lymphoseek and RIGScan product candidates, which could cause our business to be severely harmed. Our product candidates are subject to extensive and rigorous government regulation. FDA regulates, among other things, the development, testing, manufacture, safety, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. None of our product candidates has been approved for sale in the United States or any foreign market. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, complex, expensive and uncertain. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to FDA for each indication to establish the product candidate's safety and efficacy. Data obtained from preclinical and clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. In light of the limited regulatory history of monoclonal antibody-based

Edgar Filing: NEOPROBE CORP - Form 10KSB

therapeutics, regulatory approvals for our products may not be obtained without lengthy delays, if at all. Any FDA or other regulatory approvals of our product candidates, once obtained, may be withdrawn. The effect of government regulation may be to:

- o delay marketing of potential products for a considerable period of time;
- o limit the indicated uses for which potential products may be marketed;
- o impose costly requirements on our activities; and
- o provide competitive advantage to other pharmaceutical and biotechnology companies.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. Outside the United States, our ability to market a product is contingent upon receiving clearances from the appropriate regulatory authorities. This foreign regulatory approval process includes similar risks to those associated with FDA approval process.

Our radiopharmaceutical product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with continuing regulations, we could lose these approvals and the sale of our products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the approval could be conditioned on us conducting additional costly post-approval studies or could limit the indicated uses included in our labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

23

If we fail to comply with the regulatory requirements of FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- o restrictions on the products, manufacturers or manufacturing processes;
- o warning letters;
- o civil or criminal penalties;
- o fines;
- o injunctions;
- o product seizures or detentions;
- o import bans;
- o voluntary or mandatory product recalls and publicity requirements;
- o suspension or withdrawal of regulatory approvals;
- o total or partial suspension of production; and

Edgar Filing: NEOPROBE CORP - Form 10KSB

- o refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

Our existing products are highly regulated and we could face severe problems if we do not comply with all regulatory requirements in the global markets in which these products are sold.

FDA regulates our gamma detection and blood flow products in the United States. Foreign countries also subject these products to varying government regulations. In addition, these 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 blood flow 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.

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 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 be unable to establish the pharmaceutical manufacturing capabilities necessary to develop and commercialize our potential products.

We do not have our own manufacturing facility for the manufacture of the radiopharmaceutical compounds necessary for clinical testing or commercial sale. We intend to rely in part on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of our potential products. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

Edgar Filing: NEOPROBE CORP - Form 10KSB

We may develop our manufacturing capacity in part by expanding our current facilities or building new facilities. Either of these activities would require substantial additional funds and we would need to hire and train significant numbers of employees to staff these facilities. We may not be able to develop manufacturing facilities that are sufficient to produce drug materials for clinical trials or commercial use. We and any third-party manufacturers that we may use must continually adhere to current Good Manufacturing Practices regulations enforced by FDA through its facilities inspection program. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, FDA will not grant approval to our product candidates. In complying with these regulations and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort on production, record-keeping and quality control to assure that our potential products meet applicable specifications and other requirements. If we or any third-party manufacturer with whom we may contract fail to maintain regulatory compliance, we or the third party may be subject to fines and/or manufacturing operations may be suspended.

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives applicable to our products and product candidates could limit our potential product revenue.

The regulations governing drug pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed and, in many of these countries, the pricing review period begins only after approval is granted. In some countries, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Although we monitor these regulations, our product candidates are currently in the development stage and we will not be able to assess the impact of price regulations for at least several years. As a result, we may obtain regulatory approval for a product in a particular country, but then be subject to price regulations that may delay the commercial launch of the product and may negatively impact the revenues we are able to derive from sales in that country.

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.

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

We expect to continue to devote significant 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 debt or equity 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 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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.

25

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

During 2003 and 2004, we completed several financings in which we issued common stock, convertible notes, warrants and other securities convertible into common stock to certain private investors and as required under the terms of those transactions, we filed registration statements with the United States Securities and Exchange Commission (SEC) under which the investors may resell common stock acquired in these transactions, as well as common stock acquired on the exercise of the warrants and convertible securities held by them, 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 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' 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.

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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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.

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.

26

In the United States, patent applications are secret until patents issue, and in foreign countries, patent applications are secret for a time after filing. 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 rights to use and disclose technical data that could preclude us from asserting trade secret rights in that data and software.

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 (OCS) 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

portion of the manufacture of our blood flow products out of Israel, we will 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 related to other grantees and may further accelerate them in the future.

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.

27

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.

Our secured indebtedness imposes significant restrictions on us, and a default could cause us to cease operations.

All of our material assets, except the intellectual property associated with our Lymphoseek and RIGS products under development, have been pledged as collateral for the \$8.1 million in principal amount of our 8% Series A Convertible Notes due December 12, 2008 (the Notes). In addition to the security interest in our assets, the Notes carry substantial covenants that impose significant requirements on us, including, among others, requirements that:

- o we pay all principal, interest and other charges on the Notes when due;
- o we use the proceeds from the sale of the Notes only for permitted purposes, such as Lymphoseek development and general corporate purposes;
- o we nominate and recommend for election as a director a person

Edgar Filing: NEOPROBE CORP - Form 10KSB

- designated by the holders of the Notes;
- o we keep reserved out of our authorized shares of common stock sufficient shares to satisfy our obligation to issue shares on conversion of the Notes and the exercise of the warrants issued in connection with the sale of the Notes;
- o we achieve annual revenues on a consolidated basis of at least \$5.4 million in 2005, \$6.5 million in 2006, and \$9.0 million in each year thereafter;
- o we maintain minimum cash balances of \$4.5 million at the end of the first six months of 2005, \$4.0 million at the end of the second six months of 2005, and \$3.5 million at the end of each six-month period thereafter; and
- o we indemnify the purchasers of the Notes against certain liabilities.

Additionally, with certain exceptions, the Notes prohibit us from:

- o amending our organizational or governing agreements and documents, entering into any merger or consolidation, dissolving the company or liquidating its assets, or acquiring all or any substantial part of the business or assets of any other person;
- o engaging in transactions with any affiliate;
- o entering into any agreement inconsistent with our obligations under the Notes and related agreements;
- o incurring any indebtedness, capital leases, or contingent obligations outside the ordinary course of business;
- o granting or permitting liens against or security interests in our assets;
- o making any material dispositions of our assets outside the ordinary course of business;
- o declaring or paying any dividends or making any other restricted payments; or
- o making any loans to or investments in other persons outside of the ordinary course of business.

28

Our ability to comply with these provisions may be affected by changes in our business condition or results of our operations, or other events beyond our control. The breach of any of these covenants would result in a default under the Notes, permitting the holders of the Notes to accelerate their maturity and to sell the assets securing them. Such actions by the holders of the Notes could cause us to cease operations or seek bankruptcy protection.

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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 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 \$0.25 per share and as high as \$1.11 per share in the last twelve months. Some of the factors leading to the volatility include:

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

29

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 December 20, 2004 was approximately 508,000 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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. Unless extended by the consent of a majority of our stockholders, the stockholder rights plan will expire under its own terms on August 28, 2005.

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.

30

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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:

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

In addition, in this report, we use words such as "anticipate," "believe," "plan," "expect," "future," "intend," 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 prospectus 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 approximately 11,300 square feet of office space at 425 Metro Place North, Dublin, Ohio, as our principal offices. The current lease term is from February 1, 2005 and ending on February 1, 2008, at a monthly base rent of approximately \$8,300 during 2005. 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, but that we may need to expand our space lease somewhat related to our radiopharmaceutical activities depending on the level of activities performed internally versus by third parties.

Our subsidiary, Cardiosonix Ltd., currently leases its office in the Kital

Edgar Filing: NEOPROBE CORP - Form 10KSB

Building at 8 Hasadna Street, Ra'anana, Israel. The lease covers approximately 350 square meters of space and expires in June 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.

31

PART II

Item 5. Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities

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
Fiscal Year 2004:			
First Quarter	\$ 1.10	\$ 0.28	\$ 0.90
Second Quarter	1.11	0.41	0.60
Third Quarter	0.60	0.35	0.53
Fourth Quarter	0.61	0.37	0.59
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

As of March 15, 2005, we had approximately 826 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 July 2004, our Board of Directors authorized the issuance of 91,086 shares of common stock to the trustees of our 401(k) employee benefit plan (the Plan) without registration. Such issuance is exempt from registration under the

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 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, 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 in 2001, we issued 449,438 shares of our common stock to Fusion as a partial payment of the commitment fee. During 2004 and 2003, we sold Fusion a total of 2,350,000 and 473,869 shares of common stock and realized net proceeds of \$1,468,874 and \$143,693, respectively. We also issued Fusion 66,129 and 6,462 shares of common stock, respectively, for commitment fees related to the sales of our common stock to them during 2004 and 2003. 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.

32

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 a note to Mr. Bupp in the principal amount of \$250,000. The note was secured by general assets of the company, excluding accounts receivable. In addition, we issued Mr. Bupp 375,000 warrants to purchase our common stock at an exercise price of \$0.13 per share, expiring in April 2008. The note bore interest at 8.5% per annum, payable monthly, and the note was originally due on June 30, 2004. On March 8, 2004, at the request of the Board of Directors, Mr. Bupp agreed to extend the due date of

Edgar Filing: NEOPROBE CORP - Form 10KSB

the note from June 30, 2004 to June 30, 2005. In exchange for extending the due date of the note, we issued Mr. Bupp an additional 375,000 warrants to purchase our common stock at an exercise price of \$0.50 per share, expiring in March 2009. On December 13, 2004, we paid the balance of the note to Mr. Bupp. Mr. Bupp's 750,000 warrants related to this transaction remain outstanding. 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 an outside investor for an additional \$250,000. In consideration for the loan, we issued a note to the investor in the principal amount of \$250,000. The note was secured by general assets of the company, excluding accounts receivable. In addition, we issued the investor 500,000 warrants to purchase our common stock at an exercise price of \$0.13 per share, expiring in April 2008. 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, the 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 investor's 500,000 warrants remain outstanding. The issuances of the note and warrants to the investor 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 the investor could resell to the public shares of common stock issuable on exercise of the warrants and conversion of the outside investor's note. The shares were included in a registration statement filed in December 2003.

During 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 paid them a monthly retainer of \$10,000, half in cash and half 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 issued them a total of 150,943 shares of common stock in payment for one half of their retainer. In addition, warrants to purchase 78,261 shares of our common stock were issued in exchange for their assistance in arranging an accounts receivable financing transaction. The warrants had an exercise price of \$0.28 per share, and were exercised on a cashless basis in exchange for 53,500 shares of our common stock in 2004. 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 upon 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 services of Trautman Wasserman were terminated in September 2003. 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.

33

In 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, expiring in October 2008, and issued the placement agents warrants to purchase 1,354,348 shares of our common stock on similar terms. During 2004, the warrant holders exercised a total of 3,230,066 warrants in exchange for 3,197,854 shares of our common stock. Of the warrants exercised in 2004, 3,134,783 were exercised in exchange for 3,134,783 shares of our common stock resulting in net proceeds of \$871,398. The remaining 95,283 warrants exercised in 2004 were exercised on a cashless basis in exchange for 63,071

Edgar Filing: NEOPROBE CORP - Form 10KSB

shares of our common stock. During the first quarter of 2005 to date, certain investors and placement agents exercised a total of 206,865 warrants and we realized proceeds of \$57,922. 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 the 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.

In December, 2004, we completed a private placement of Convertible Promissory Notes in an aggregate principal amount of \$8.1 million with Biomedical Value Fund, L.P., Biomedical Offshore Value Fund, Ltd. and David C. Bupp (our President and CEO). Biomedical Value Fund, L.P. and Biomedical Offshore Value Fund, Ltd. are funds managed by Great Point Partners, LLC. The notes bear interest at 8% per annum and are freely convertible into shares of our common stock at a price of \$0.40 per share. Neoprobe may force conversion of the notes prior to their stated maturity under certain circumstances. The conversion price represents the ten-day volume weighted average trading price of our common stock through December 10, 2004. As part of this transaction, we issued the investors 10,125,000 warrants to purchase our common stock at an exercise price of \$0.46, expiring in December 2009. In connection with this financing, we also issued 1,600,000 warrants to purchase our common stock to placement agents, containing substantially identical terms to the warrants issued to the investors. 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 the terms of the stock purchase agreements, in December 2004 we filed a registration statement under which the investors and placement agents may resell the shares of common stock to the public.

34

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

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 physicians. We currently have two lines of medical devices that we are actively marketing, our neo2000(R) gamma detection systems and the Quantix line of blood flow measurement devices of our subsidiary, Cardiosonix. In addition to our medical device products, we have two radiopharmaceutical products, RIGScan(R) CR and LymphoseekTM, in the advanced phases of clinical development.

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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 and RIGS(R) (radioimmunoguided surgery); however, these technologies are not anticipated to generate any significant revenue for us during 2005. In addition, we cannot assure you that these products will ever obtain marketing clearance from the appropriate regulatory bodies.

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. We expect revenue from our gamma device line for 2005 to be consistent with 2004, and we expect revenue from our Quantix(R) blood flow measurement products to increase substantially over the prior years due to the product refinements recently introduced related to our Quantix/ORTM system, although the ultimate amount of revenue achieved will be greatly dependent upon physician response to these refinements.

We expect 2005 to be a year of promising developments for Neoprobe; however, we expect that we will need to make investments in certain aspects of our technologies in order to position us for the success we believe is possible. To that end, we anticipate spending approximately \$5 million on the development of Lymphoseek over the next eighteen months in order to prepare for the submission of a new drug application to the U.S. Food and Drug Administration (FDA) in mid-2006. We also anticipate the marketing and commercialization support development expenses necessary to support our Quantix blood flow measurement commercialization efforts in 2005, excluding general and administrative costs, will exceed \$1.5 million. We anticipate some development expenses in 2005 related to the innovations we plan for our gamma device products as well, although we do not currently expect our investment in our gamma device line to differ significantly from 2004. We also expect to incur some development expenses in 2005 related to our RIGS radiopharmaceutical product development although we intend to defer any major expenses until we identify a partner to assist us in the development and commercialization of RIGScan CR. As a result, although we expect to see positive movement in all our lines of business in 2005, we will likely yet show a loss for the year due to our market and product development efforts.

35

As of December 31, 2004, our cash on hand was \$9.8 million. During 2004, we used \$825,000 in cash to fund our operations. We believe our currently available capital resources will be adequate to sustain our device operations at current levels through 2006. 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 unable to arrange a suitable strategic opportunity, we may need to modify 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

Hundreds of articles have been published in recent years in peer-reviewed journals on the topics of sentinel lymph node biopsy and intraoperative lymphatic mapping (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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 believe our development efforts related to Lymphoseek may be instrumental in expanding ILM into other indications. 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 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 decline in the adoption rate of ILM or the development of alternative technologies by competitors may negatively impact our sales volumes, and therefore, revenues and net income in 2005.

During 2004, our primary gamma device marketing partner, Ethicon Endo-Surgery, Inc. (EES), a Johnson and Johnson company, exercised the first of its two options to extend the termination date of our distribution agreement with them through the end of 2006. As of December 31, 2004, we had approximately \$1.5 million in committed orders from EES that extend through late April 2005. We believe that total 2005 purchases of base neo2000 systems by EES should be consistent with their 2004 purchase levels. We cannot assure you, however, that EES' product purchases beyond those firmly committed through mid-2005 will indeed occur or that the prices we realize will not be affected by increased competition.

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 continue to believe in the technical and user-friendly superiority of our products, the competitive landscape continues to evolve 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, remained relatively steady during 2004 as compared to 2003. The price that we received during 2004 was 20% above the floor pricing for base systems. As a result, 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 attained in 2004 will result in continued profitability for our gamma device business line for 2005.

36

Our Outlook for our Gamma Detection Radiopharmaceuticals

Our outlook for the two potential products in our radiopharmaceutical portfolio has evolved significantly over the last several months. During 2004, researchers

Edgar Filing: NEOPROBE CORP - Form 10KSB

from 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.

During 2004, we prepared and submitted an investigational new drug (IND) application and a draft clinical protocol to FDA for a pivotal trial to support the marketing clearance of Lymphoseek. FDA has accepted our IND submission for Lymphoseek. With the establishment of the corporate IND, responsibility for the clinical and commercial development of Lymphoseek has been officially transferred from UCSD to Neoprobe. Neoprobe has therefore assumed clinical responsibility for the development of Lymphoseek from UCSD. FDA has provided guidance that they would prefer to have Lymphoseek evaluated in a multi-center clinical study to confirm the clinical findings observed by the UCSD researchers to be followed by a confirmation Phase III study that would be initiated with the final cGMP material. Neoprobe intends to commence enrollment in this multi-institutional study as soon as the appropriate regulatory and institutional review board clearances are received. We believe enrollment in the multi-center study may begin by the end of the second quarter of 2005. The study will be conducted at some of the nation's leading cancer treatment institutions. FDA guidelines also require Neoprobe to complete some additional preclinical activities prior to the initiation of the multi-center trials. Neoprobe has initiated this preclinical work in parallel to its other development activities and recently submitted an IND amendment containing a complete draft of the proposed multi-center evaluation for Lymphoseek. We cannot assure you, however, that this product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

Our RIGS technology, which had been essentially inactive since the failure 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 CR49. While this renewed interest is by no means an assurance that full-scale development will be invigorated, we had a meeting in April 2004 to review some of this information with FDA, to determine the appropriate next steps for the development of the product and to outline a possible development timeline. The April 2004 meeting with FDA was an important event in the re-activation of the RIGS program. The meeting was very helpful from a number of aspects: we confirmed that the RIGS biologic license application (BLA) remains active and open. We believe this will improve both the cost effectiveness and timeliness of future regulatory submissions for RIGScan CR. Additionally, FDA preliminarily confirmed that the BLA may be applicable to the general colorectal population; and not just the recurrent colorectal market as applied for in 1996. Applicability to a general colorectal population could result in a greater market potential for the product than if applicable to just the recurrent population. During the meeting, FDA indicated that it would consider possible diagnostic and prognostic indications for RIGScan CR and that survival data from one of our earlier Phase III studies could be supportive of a prognostic indication. Our initial submission included a proposed clinical trial design with objectives to demonstrate both diagnostic and prognostic/therapeutic endpoints.

In October 2004, Neoprobe received a response from FDA that the prognostic/therapeutic trial design appeared to meet their guidelines, but they requested additional information concerning the diagnostic clinical objective. FDA's response to our clinical submission included an invitation for Neoprobe to

Edgar Filing: NEOPROBE CORP - Form 10KSB

seek a special protocol assessment (SPA) of its proposed Phase III study. Neoprobe intends to seek a SPA review of the complete Phase III package including the clinical protocol, training materials and data collection forms later this year. In concert with its meetings with FDA, we met with representatives of the European regulatory body, the EMEA, to seek guidance for the RIGScan CR program in Europe. The guidance from the EMEA was consistent with the input from FDA with the additional recommendation that any future clinical studies be conducted with the humanized version of the RIGScan CR antibody. It is possible that the regulatory pathway may continue to evolve as we seek to reach a consensus with the regulatory agencies on the reactivation of the BLA for RIGScan CR.

37

In addition, the RIGScan CR biologic 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 FDA for their evaluation before approval could be considered. We have initiated 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 radiolabeling capabilities for the CC49 antibody in order to meet the regulatory needs for the RIGScan CR product.

In parallel with our discussions with the regulatory authorities, we have discussed the clinical and regulatory strategy for RIGScan CR with reimbursement consultants who provided us with valuable input regarding the potential target pricing for a RIGScan product. Our consultants have advised us that if we proceed with our original plans to seek an earlier conditional clearance for the potential diagnostic indications for RIGScan CR then followed by clearance for the prognostic/therapeutic indication we might significantly limit the ultimate potential price for the prognostic/therapeutic product. However, since we have announced that it is our intention to develop RIGScan CR in cooperation with a development partner, we intend to make the decision on which indications to seek clearance for jointly with a partner.

We are encouraged by the recent developments regarding 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 and the completion of the survival analysis proposed to FDA at the April 2004 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 five 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 do 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 FDA or the EMEA will clear our RIGS products for marketing or that any such products will be successfully introduced or achieve market acceptance.

Our Outlook for our Blood Flow Measurement Products

Our efforts concerning the Quantix products in 2005 will include some product transition efforts developmental refinements to the Quantix/NDTM 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

for the Quantix/OR. In addition, we have agreements completed or pending with independent cardiovascular sales organizations for many 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 cardiovascular, vascular surgery and neurosurgical markets.

We anticipate spending a significant amount of time and effort in 2005 to market the Cardiosonix blood flow products to a wider market. We will need to continue the management of relationships with thought leaders in the cardiac surgery 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 commercial feedback during the 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 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.

38

We expect sales of blood flow products for 2005 to be higher than 2004 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 2005 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 2005.

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 will be significantly affected by our decision to fund Lymphoseek development activities internally.

We anticipate generating a net profit from the sale of our gamma detection devices in 2005; however, we expect to show a loss for our blood flow device product line for 2005 due to continued research and development and 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 2005 to be less than the loss incurred in 2004. 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 2005 will be affected by the amount of development for radiopharmaceutical products. If we are unsuccessful in achieving significant commercial sales of the Quantix/OR product in 2005, or if we modify our business plan and decide to carry out RIGS development internally, our estimates and our business plan will likely need to be modified.

As a result of our decision to fund Lymphoseek development internally, we do not expect to achieve operating profit during 2005. In addition, our net loss and earnings per share will likely be significantly impacted by the non-cash interest expense we expect to record related to the accounting treatment for the beneficial conversion feature of the convertible debt and for the warrants issued in connection with the private placement we completed in December 2004. Also, we cannot assure you that our current or potential new products will be

Edgar Filing: NEOPROBE CORP - Form 10KSB

successfully commercialized or that we will achieve significant product revenues or that we will achieve or be able to sustain profitability in the future.

Results of Operations

We reported revenues for 2004 of \$6.0 million compared to \$6.5 million in the prior year. The decrease in revenue in 2004 versus 2003 is the combined result of non-cash EES license revenue recognition that ended in September 2004, \$146,000 in reimbursed research and development in 2003, and a \$194,000 decline in sales of our blood flow measurement products. Sales revenue from our gamma detection product line remained steady from 2003 to 2004.

Our overall gross profit for fiscal year 2004 increased to 61% of total revenues compared to 52% of total revenues in 2003. Gross margins on net product sales were 56% of net sales in 2004, as compared to 44% of net product sales in 2003. The increase in gross margins was due primarily to a 28% decrease in manufacturing cost per gamma detection system for the year.

39

Results for 2004 also reflect the efforts made in the development of our gamma detection radiopharmaceutical products, RIGScan CR and Lymphoseek. Accordingly, our research and development costs for 2004 increased to \$2.5 million compared to \$1.9 million in 2003. Consolidated general and administrative expenses remained constant at \$3.2 million in 2004 compared to \$3.1 million in 2003. Major expense categories as a percentage of net sales increased from 2003 to 2004 due to the decrease in sales of our blood flow monitoring devices. Research and development expenses, as a percentage of sales, increased to 46% in 2004 from 34% in 2003 due to decreased net sales coupled with increased expenses related to the development of our gamma detection drug products. Selling, general and administrative expenses, as a percentage of sales, increased to 59% in 2004 from 56% in 2003 due largely to the decrease in net sales revenue. Due to the ongoing development activities of the company, research and development expenses are expected to be higher as a percentage of sales for 2005 than they were in 2004. In addition, as we move forward with commercialization activities related to the Quantix product line, selling, general and administrative expenses as a percentage of sales are expected to increase in 2005 over 2004.

Years Ended December 31, 2004 and 2003

Net Sales and Margins. Net sales decreased \$212,000, or 4%, to \$5.4 million in 2004 from \$5.6 million in 2003. Gross margins on net sales increased to 56% of net sales for 2004 compared to 44% of net sales for 2003, due primarily to a 28% decrease in the manufacturing costs of our gamma detection devices.

The decrease in net sales was primarily the result of decreased revenue from our blood flow monitoring devices. Sales revenue from our gamma detection product line remained steady from 2003 to 2004. 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 base system price at which we sell neo2000 systems to EES changed less than 1% from 2003 to 2004.

The increase in gross margins was primarily due to the lower manufacturing costs as a result of transferring to a new gamma device manufacturer coupled with gamma device design changes that were implemented during the first quarter of 2004. In addition, we recorded a \$107,000 impairment charge during 2004 related to Quantix inventory that we determined to be obsolete. This impairment charge had a 2% negative impact on our gross margins for 2004.

License and Other Revenue. License and other revenue for 2004 and 2003 included

Edgar Filing: NEOPROBE CORP - Form 10KSB

\$600,000 and \$800,000, respectively, from the pro-rata recognition of license fees related to the distribution agreement with EES. These license fees were fully amortized into income as of the end of the third quarter of 2004. License and other revenue in 2003 also included \$146,000 from the reimbursement by EES of certain product development costs.

Research and Development Expenses. Research and development expenses increased \$560,000, or 30%, to \$2.5 million during 2004 from \$1.9 million in 2003. Research and development expenses in 2004 included approximately \$489,000 in gamma detection drug development costs, \$404,000 related to our gamma detection devices and \$1.6 million related to the Quantix products. This compares to expenses of \$56,000, \$454,000 and \$1.4 million in these relative segment categories in 2003. The changes in each segment were primarily due to (i) efforts to support the re-initiation of our RIGScan CR research effort and to move our development of Lymphoseek forward, (ii) development activities related to updated versions of our neo2000 control unit and detector probes, and (iii) the costs of product refinement activities related to the Quantix/OR offsetting cost savings from headcount reductions at our facility in Israel, respectively.

Selling, General and Administrative Expenses. Selling, general and administrative expenses remained relatively steady at \$3.2 million during 2004 compared to \$3.1 million during 2003. Increases in compensation costs and certain overhead costs such as professional services and taxes were offset by decreases in other overhead costs such as depreciation and amortization, facilities expenses and bad debts. Selling, general and administrative expenses in 2004 and 2003 included \$7,000 and \$30,000, respectively, in impairment expense related to intellectual property that we did not believe had ongoing value to our business.

Other Income (Expenses). Other expenses increased \$1.4 million to \$1.5 million during 2004 from \$188,000 during 2003. The primary reason for the increase was a \$1.2 million increase in warrant liability resulting from the accounting treatment for the warrants we issued in connection with the private placement of convertible debt we completed in December 2004. In addition, we recorded an increase of \$194,000 in interest expense on debt financings entered into during 2004 and 2003. Of this interest expense, \$268,000 and \$93,000 in 2004 and 2003, respectively, was non-cash in nature related to the amortization of debt discounts resulting from the warrants and beneficial conversion features of the convertible debt. Other expenses during 2003 included \$50,000 in interest expense related to the factoring of our accounts receivable.

40

Liquidity and Capital Resources

Operating Activities. Cash used in operations decreased \$989,000 to \$825,000 during 2004 from \$1.8 million during 2003. Working capital increased \$7.9 million to \$10.4 million at December 31, 2004 as compared to \$2.5 million at December 31, 2003. The current ratio increased to 11.3:1 at December 31, 2004 from 2.6:1 at December 31, 2003. The increase in working capital was primarily related to cash received from debt financing arrangements and sales of common stock.

Cash balances increased to \$9.8 million at December 31, 2004 from \$1.6 million at December 31, 2003, primarily due to the cash generated from debt financing arrangements and sales of common stock, offset by decreased sales and the development effort related to our gamma detection drugs in 2004.

Accounts receivable decreased to \$412,000 at December 31, 2004 from \$1.1 million at December 31, 2003 due primarily to lower sales in December 2004 than December 2003 coupled with the timing of purchases and payments by EES. During the third

Edgar Filing: NEOPROBE CORP - Form 10KSB

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. Accounts receivable at December 31, 2004 and 2003 also included approximately \$24,000 and \$350,000, respectively, related to our annual transfer price reconciliation with EES. We expect overall receivable levels will continue to fluctuate in 2005 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 \$855,000 at December 31, 2004 from \$1.0 million at December 31, 2003. Raw materials decreased compared to the prior period due to obsolescence related to design changes and production of our blood flow measurement devices. This decrease was offset by increases in our stock of gamma detection and blood flow device finished goods due to decreased sales in December 2004 as compared to December 2003. In addition, our inventory of gamma device finished goods at the end of 2003 was lower than normal because we were in the process of changing contract manufacturers of our gamma detection devices to a new contract manufacturer. We expect inventory levels to increase during 2005 as we complete finished blood flow devices from our inventory of raw materials.

Investing Activities. Cash used in investing activities remained steady at \$111,000 during 2004 compared to \$109,000 during 2003. Capital expenditures during 2004 were primarily purchases of technology infrastructure. 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 needs for 2005 are expected to increase over 2004 as we start up blood flow product production at our contract manufacturer.

Financing Activities. Financing activities provided \$9.2 million in cash in 2004 versus \$2.8 million during 2003. Proceeds from the issuance of common stock were \$2.3 million and \$2.9 million in 2004 and 2003, respectively. Proceeds from notes payable were \$7.4 million and \$458,000 during 2004 and 2003, respectively. Proceeds from sales of accounts receivable and subsequent repayments totaled \$914,000 during 2003. Payments of notes payable were \$271,000 higher during 2004 as compared to the same period in 2003, primarily due to the repayment of a note to our CEO.

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 partial payment of the commitment fee. During 2004 and

Edgar Filing: NEOPROBE CORP - Form 10KSB

2003, we sold Fusion a total of 2,350,000 and 473,869 shares of common stock and realized net proceeds of \$1,468,874 and \$143,693, respectively. We also issued Fusion 66,129 and 6,462 shares of common stock, respectively, for commitment fees related to the sales of our common stock to them during 2004 and 2003.

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 to Mr. Bupp in the principal amount of \$250,000. The note was secured by general assets of the company, excluding accounts receivable. In addition, we issued Mr. Bupp 375,000 warrants to purchase our common stock at an exercise price of \$0.13 per share, expiring in April 2008. The per share 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. The note bore interest at 8.5% per annum, payable monthly, and was originally due on June 30, 2004. On March 8, 2004, at the request of the Board of Directors, Mr. Bupp agreed to extend the due date of the note from June 30, 2004 to June 30, 2005. In exchange for extending the due date of the note, we issued Mr. Bupp an additional 375,000 warrants to purchase our common stock at an exercise price of \$0.50 per share, expiring in March 2009. 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. On December 13, 2004, we paid the balance of the note to Mr. Bupp.

During April 2003, we also completed a convertible bridge loan agreement with an outside investor for an additional \$250,000. In consideration for the loan, we issued a note to the investor in the principal amount of \$250,000. The note was secured by general assets of the company, excluding accounts receivable. In addition, we issued the investor 500,000 warrants to purchase our common stock at an exercise price of \$0.13 per share, expiring in April 2008. The per share 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, the investor converted the entire balance of the note into 1.1 million shares of common stock according to the conversion terms of the agreement.

During 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 paid 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 issued them a total of 150,943 shares of common stock in payment for one half of their retainer. In addition, 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 had an exercise price of \$0.28, and were exercised in exchange for 53,500 shares of our common stock in 2004. 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.

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 issued Trautman Wasserman a

Edgar Filing: NEOPROBE CORP - Form 10KSB

total of 27,199 shares of common stock in payment for one half of their retainer. The services of Trautman Wasserman were terminated in September 2003.

In November 2003, we executed common stock purchase agreements with third parties introduced to us by another 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, expiring in October 2008, and issued the placement agents warrants to purchase 1,354,348 shares of our common stock on similar terms. 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. During 2004, certain investors and placement agents exercised a total of 3,230,066 warrants related to this placement resulting in the issuance of 3,197,854 shares of our common stock and we realized net proceeds of \$871,398. During the first quarter of 2005 to date, certain investors and placement agents exercised a total of 206,865 warrants and we realized proceeds of \$57,922.

In December 2004, we completed a private placement of Convertible Promissory Notes in an aggregate principal amount of \$8.1 million with Biomedical Value Fund, L.P., Biomedical Offshore Value Fund, Ltd. and David C. Bupp (our President and CEO). Biomedical Value Fund, L.P. and Biomedical Offshore Value Fund, Ltd. are funds managed by Great Point Partners, LLC. The notes bear interest at 8% per annum and are freely convertible into shares of our common stock at a price of \$0.40 per share. Neoprobe may force conversion of the notes prior to their stated maturity under certain circumstances. The conversion price represents the ten-day volume weighted average trading price of our common stock through December 10, 2004. As part of this transaction, we issued the investors 10,125,000 warrants to purchase our common stock at an exercise price of \$0.46, expiring in December 2009. The fair value of the warrants issued to the investors was \$1,315,000 on the date of issuance and was determined by a third-party valuation expert using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.4%, volatility of 50% and no expected dividend rate. In connection with this financing, we also issued 1,600,000 warrants to purchase our common stock to the placement agents, containing substantially identical terms to the warrants issued to the investors. The fair value of the warrants issued to the placement agents was \$208,014 using the Black-Scholes option pricing model with the same assumptions used to determine the fair value of the warrants issued to the investors. The intrinsic value of the conversion feature of the notes was estimated at \$1,315,000 based on the effective conversion price at the date of issuance.

Our future liquidity and capital requirements will depend on a number of factors, including our ability to raise additional capital in a timely manner through additional investment, expanded market acceptance of our current products, our ability to complete the commercialization of new products, 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 FDA and other international regulatory bodies, and intellectual property protection. We believe we now have adequate capital to assure that we can properly support our current business goals and objectives for 2005 and into 2006. Our near-term priorities to commence multi-center trials for our Lymphoseek product, support the launch the reengineered version of the Quantix/OR products, identify a development and commercialization partner for our RIGS technology, complete a technology assessment of our ACT technology and continue to innovate our gamma detection product line. 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.

Edgar Filing: NEOPROBE CORP - Form 10KSB

Contractual Obligations and Commercial Commitments

The following table presents our contractual obligations and commercial commitments as of December 31, 2004.

Contractual Cash Obligations	Payments Due By Period			
	Total	Less than 1 Year	1 - 3 Years	4 - 5 Years
Capital Leases(1)	\$ 53,418	\$ 18,308	\$ 27,810	7,
Operating Leases(2)	377,116	145,562	223,241	8,
Unconditional Purchase Obligations(3)	2,129,045	1,391,746	737,299	
Long-Term Debt	10,674,254	662,211	1,296,000	8,716,
Total Contractual Cash Obligations	\$13,233,833	\$ 2,217,827	\$ 2,284,350	\$ 8,731,

- (1) In February 2005, we entered into a four-year capital lease agreement for office equipment. The lease includes new equipment and refinanced equipment that had been under another capital lease. The net additional lease payments total approximately \$5,000 per year.
- (2) In February 2005, we entered into a three-year operating lease agreement for additional office space. The additional lease payments total approximately \$22,000 per year.
- (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 two years.

Recent Accounting Developments

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. This statement amends the guidance in ARB No. 43 Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB No. 43, Chapter 4, previously stated that ". . . under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal to require treatment as a current period charge..." This statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this statement will be effective for inventory costs during fiscal years beginning after June 15, 2005. Neoprobe does not believe that the adoption of this statement will have a material impact on its financial condition or results of operations.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based

Edgar Filing: NEOPROBE CORP - Form 10KSB

Compensation (SFAS No. 123R). SFAS No. 123R supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends SFAS No. 95, Statement of Cash Flows. Generally, the approach in SFAS No. 123R is similar to the approach described in SFAS No. 123. However, SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. We must adopt SFAS No. 123R for interim or annual reporting periods beginning after December 15, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We expect to adopt SFAS No. 123R on January 1, 2006.

44

As permitted by SFAS No. 123, Neoprobe currently accounts for share-based payments to employees using APB Opinion No. 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS No. 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall cash position. The impact of adoption of SFAS No. 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future and the assumptions for the variables which impact the computation. However, had we adopted SFAS No. 123R in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net loss and loss per share in Note 1(k) to our consolidated financial statements. SFAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Nonmonetary Assets--An Amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions (SFAS No. 153). SFAS No. 153 eliminates the exception from fair value measurement for nonmonetary exchanges of similar productive assets in paragraph 21(b) of APB Opinion No. 29, Accounting for Nonmonetary Transactions, and replaces it with an exception for exchanges that do not have commercial substance. SFAS No. 153 specifies that a nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for fiscal periods beginning after June 15, 2005 and is required to be adopted by Neoprobe beginning January 1, 2006. Neoprobe is currently evaluating the effect that the adoption of SFAS No. 153 will have on its consolidated results of operations and financial condition but does not expect it to have a material impact.

Critical Accounting Policies

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 1% of total revenues for 2004 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base these estimates and assumptions upon historical experience and existing, known circumstances. Actual results could differ from those estimates. Specifically, management may make significant estimates in the following areas:

45

- o 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 customers' 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.
- o Inventory Valuation. We value our inventory at the lower of cost (first-in, first-out method) or market. Our valuation reflects our estimates of 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 launch strategies, product recalls and variation in product utilization all impact the estimates related to excess and obsolete inventory.
- o 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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, 2004, 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.

- o 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.
- o Fair Value of Warrant Liability. Current generally accepted accounting principles require that the warrants issued in connection with our December 2004 placement of convertible promissory notes be classified as a liability due to provisions contained in the underlying securities purchase agreement. As a liability, the warrants are considered a derivative instrument that must be periodically "marked to market" on our balance sheet. We estimate the fair value of the warrants as of each balance sheet date based on the Black-Scholes option pricing model. Because the outcome of the Black-Scholes calculation is highly dependent on the price of our common stock as well as the estimated future volatility of the underlying common stock, and our stock is very volatile, the effect of marking the warrant liability to "market" may result in significant variations in other income (expenses) we record on a periodic basis and therefore on the net income (loss) we report.

46

Other Items Affecting Financial Condition

At December 31, 2004, we had U.S. net operating tax loss carryforwards and tax credit carryforwards of approximately \$91.4 million and \$4.2 million, respectively, available to offset or reduce future income tax liability, if any, through 2024. 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, 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 39 through 43 of this report.

Item 7. Financial Statements

Our consolidated financial statements, and the related notes, together with the report of KPMG LLP dated March 31, 2005, are set forth at pages F-1 through F-25 attached hereto.

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 fourth quarter 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 affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 8B. Other Information.

None.

47

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 2005 Annual Meeting:

Carl J. Aschinger, Jr., age 66, has served as a director of our Company since June 2004. Mr. Aschinger is the Chairman and Chief Executive Officer of Columbus Show Case Co., a privately-held company that manufactures showcases for the retail industry. Mr. Aschinger also serves on the Board of Directors and as Chairman of the Audit Committee of Pinnacle Data Systems, a publicly-traded company that provides software and hardware solutions to original equipment manufacturers. Mr. Aschinger also serves on the Board of Directors and as Chairman of the Audit Committee of Wilson-Bohannon, a privately-held company that manufactures padlocks. Mr. Aschinger is a former director of Liqui-Box Corporation and Huntington National Bank as well as other privately-held ventures and has served on boards or advisory committees of several not-for-profit organizations.

Nancy E. Katz, age 45, has served as a director of our Company since January 2001. Ms. Katz currently is an independent health care business consultant. Ms. Katz served as President, Chief Executive Officer and director of Calypte Biomedical Corporation (Calypte) until June 2003. Ms. Katz joined Calypte in October 1999 as President, Chief Operating Officer and Chief Financial Officer. Prior to joining Calypte, Ms. Katz served as President of Zila Pharm Inc. From

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 65, has served as a director of our Company since January 2002. Mr. Miller serves as Chairman of the Audit Committee. 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 board of one other privately-held company. 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 directors' terms continue until the 2006 Annual Meeting:

Kirby I. Bland, M.D., age 63, has served as a director of our Company since May 2004. Dr. Bland currently serves as Professor and Chairman and Fay Fletcher Kerner Professor and Chairman, Department of Surgery of the University of Alabama at Birmingham (UAB) School of Medicine since 1999 and 2002, respectively, Deputy Director of the UAB Comprehensive Cancer Center since 2000 and Senior Scientist, Division of Human Gene Therapy, UAB School of Medicine since 2001. Prior to his appointments at UAB, Dr. Bland was J. Murry Breadsley Professor and Chairman, Professor of Medical Science, Department of Surgery and Director, Brown University Integrated Program in Surgery at Brown University School of Medicine from 1993 to 1999. Prior to his appointments at Brown University, Dr. Bland was Professor and Associate Chairman, Department of Surgery, University of Florida College of Medicine from 1983 to 1993 and Associate Director of Clinical Research at the University of Florida Cancer Center from 1991 to 1993. Dr. Bland held a number of medical staff positions at the University of Louisville, School of Medicine from 1977 to 1983 and at M. D. Anderson Hospital and Tumor Institute from 1976 to 1977. Dr. Bland is a member of the Board of Governors of the American College of Surgeons (ACS), a member of the ACS' Advisory Committee, Oncology Group (ACOSOG), a member of the ACS' American Joint Committee on Cancer Task Force and serves as Chairman of the ACS' Breast Disease Site Committee, COC. Dr. Bland is a past President of the Society of Surgical Oncology. Dr. Bland received his B.S. in Chemistry/Biology from Auburn University and a M.D. degree from the University of Alabama, Medical College of Alabama.

48

J. Frank Whitley, Jr., age 62, 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.

The following directors' terms continue until the 2007 Annual Meeting:

Edgar Filing: NEOPROBE CORP - Form 10KSB

Reuven Avital, age 53, 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, and 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 55, 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 80, 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 also serves on the Board of Directors and the compensation committee of the Board of Directors of Calypte Biomedical Corporation (Calypte), a publicly held corporation. Dr. Krevans has a B.S. degree and a M.D. degree, both from New York University.

49

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
----	---	-----
Anthony K. Blair	44	Vice President, Manufacturing Operations
Carl M. Bosch	48	Vice President, Research and Development
Rodger A. Brown	53	Vice President, Regulatory Affairs and Quality Assurance
Brent L. Larson	41	Vice President, Finance; Chief Financial Officer; Treasurer and Secretary
Douglas L. Rash	61	Vice President, Marketing

Anthony K. Blair has served as Vice President, Manufacturing Operations of our Company since July 2004. Mr. Blair has 16 years of experience in the medical

Edgar Filing: NEOPROBE CORP - Form 10KSB

device industry. Prior to joining our Company, he served as Vice President, Manufacturing Operations of Enpath Medical, Lead Technologies Division, formerly known as Biomec Cardiovascular, Inc. from 2002 to June 2004. From 1998 through 2001, Mr. Blair led the manufacturing efforts at Astro Instrumentation, a medical device contract manufacturer. From 1989 to 1998 at Ciba Corning Diagnostics (now Bayer), Mr. Blair held managerial positions including Operations Manager, Materials Manager, Purchasing Manager and Production Supervisor. From 1985 to 1989, Mr. Blair was employed by Bailey Controls and held various positions in purchasing and industrial engineering. Mr. Blair started his career at Fisher Body, a division of General Motors, in production supervision. Mr. Blair has a B.B.A. degree in management and labor relations from Cleveland State University.

Carl M. Bosch has served as Vice President, Research and Development of our Company since March 2000. Prior to that, Mr. Bosch served as our Director, 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.

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.

Douglas L. Rash has served as Vice President, Marketing of our Company since January 2005. Prior to that, Mr. Rash was Neoprobe's Director, Marketing and Product Management from March to December 2004. Before joining our Company, Mr. Rash served as Vice President and General Manager of MTRE North America, Inc. from 2000 to 2003. From 1994 to 2000, Mr. Rash served as Vice President and General Manager (Medical Division) of Cincinnati Sub-Zero, Inc. From 1993 to 1994, Mr. Rash was Executive Vice President of Everest & Jennings International, Ltd. During his nine-year career at Gaymar Industries, Inc. from 1984 to 1993, Mr. Rash held positions as Vice President and General Manager (Clinicare Division) and Vice President, Marketing and Sales (Acute Care Division). From 1976 to 1984, Mr. Rash held management positions at various divisions of British Oxygen Corp. Mr. Rash has a B.S. degree in Business Administration with a minor in Chemistry from Wisconsin State University.

50

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

Edgar Filing: NEOPROBE CORP - Form 10KSB

during the fiscal year ended December 31, 2004, except for Carl Aschinger, who had two late Form 4 filings, and Anthony Blair, who had one late Form 3 and one late Form 4 filing.

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 is posted on our website at www.neoprobe.com. The code of business conduct and ethics may be also obtained free of charge by writing to Neoprobe Corporation, Attn: Chief Financial Officer, 425 Metro Place North, Suite 300, Dublin, Ohio 43017.

Audit Committee Financial Expert

The Board of Directors of Neoprobe has determined that Fred B. Miller, a member of the Audit Committee, qualifies as Neoprobe's audit committee financial expert under Item 401 of Regulation S-B under the Securities Act of 1933, and that he is independent, as that term is defined in Item 7(d)(3) of Schedule 14A under the Securities Exchange Act of 1934.

51

Item 10. Executive Compensation

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 highest paid 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			Other	Compe Restric Stock Aw ($\$$)
		Salary	Bonus			
Carl M. Bosch Vice President, Research and Development	2004	\$ 138,375	\$ 6,000	\$ 2,887 (a)	--	
	2003	135,125	--	6,573 (a)	--	
	2002	129,375	--	3,093 (a)	--	
Rodger A. Brown Vice President, Regulatory Affairs/ Quality Assurance	2004	\$ 117,300	\$ 2,500	\$ --	--	
	2003	125,316	--	--	--	
	2002	105,417	--	--	--	
David C. Bupp President and Chief Executive Officer	2004	\$ 271,250	\$ 15,000	\$ 4,100 (b)	--	
	2003	222,167	32,500	31,090 (b)	--	
	2002	297,083	--	5,738 (b)	--	
Brent L. Larson Vice President, Finance and Chief Financial Officer	2004	\$ 137,700	\$ 6,000	\$ 2,874 (c)	--	
	2003	135,125	--	11,733 (c)	--	
	2002	129,375	--	2,993 (c)	--	

Edgar Filing: NEOPROBE CORP - Form 10KSB

- (a) Amounts represent solely matching contribution under the Neoprobe Corporation 401(k) Plan (the Plan), except for 2003, which includes \$3,870 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 \$9,030 related to the vesting of restricted stock.

52

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 2004 fiscal year.

Individual Grants				
Name	Number of Securities Underlying Options Granted (shares)	Percent of Total Options Granted to Employees in Fiscal Year	Exercise Price Per Share	Expiration Date (e)
Carl M. Bosch	70,000 (a)	4%	\$ 0.30 (b)	1/7/14
	50,000 (a)	3%	\$ 0.49 (c)	7/28/14
	50,000 (a)	3%	\$ 0.39 (d)	12/10/14
Rodger A. Brown	70,000 (a)	4%	\$ 0.30 (b)	1/7/14
	50,000 (a)	3%	\$ 0.49 (c)	7/28/14
	40,000 (a)	2%	\$ 0.39 (d)	12/10/14
David C. Bupp	150,000 (a)	9%	\$ 0.30 (b)	1/7/14
	150,000 (a)	9%	\$ 0.49 (c)	7/28/14
	200,000 (a)	12%	\$ 0.39 (d)	12/10/14
Brent L. Larson	70,000 (a)	4%	\$ 0.30 (b)	1/7/14

Edgar Filing: NEOPROBE CORP - Form 10KSB

50,000 (a)	3%	\$ 0.49 (c)	7/28/14
50,000 (a)	3%	\$ 0.39 (d)	12/10/14

- (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 2004 was \$0.29 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 2.8%, volatility of 146% and no expected dividend rate.
- (c) The per share weighted average fair value of these stock options during 2004 was \$0.49 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 3.3%, volatility of 139% and no expected dividend rate.
- (d) The per share weighted average fair value of these stock options during 2004 was \$0.32 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 3.3%, volatility of 80% and no expected dividend rate.
- (e) 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.

53

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, 2004). There were no stock options exercised by the Named Executives during the fiscal year ended December 31, 2004.

Name	Number of Securities Underlying Unexercised Options at Fiscal Year-End:		Value of Unexercised In-the-Money Options at Fiscal Year-End:
----	Exercisable/Unexercisable		Exercisable/Unexercisable (1)
-----	-----		-----
Carl M. Bosch	176,668	/ 233,332	\$86,534 / \$137,666
Rodger A. Brown	171,168	/ 223,332	\$80,634 / \$131,766
David C. Bupp	586,668	/ 773,332	\$316,634 / \$397,266
Brent L. Larson	233,868	/ 233,332	\$104,234 / \$137,666

- (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 \$0.59. An option is in-the-money if the fair market value of the underlying shares exceeds the exercise price of the option.

Compensation of Non-Employee Directors

Edgar Filing: NEOPROBE CORP - Form 10KSB

We paid non-employee directors a quarterly retainer of \$1,500 for participation in board or committee meetings during 2004. We also reimbursed non-employee directors for travel expenses for meetings attended during 2004. In addition, each non-employee director received 40,000 options to purchase common stock as a part of our annual stock incentive grants, and the Chairman of the Board and the Chairman of the Audit Committee each received an additional 40,000 options for their services in those capacities. Options granted to purchase common stock vest on the first anniversary of the date of grant and have an exercise price equal to not less than the closing 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. Effective January 1, 2005, Mr. Bupp's annual base salary was increased to \$290,000. 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 \$15,000 relating to fiscal year 2004.

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

- o 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);
- o the term of Mr. Bupp's employment agreement expires; or

54

- o 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:

- o 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;
- o 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;

Edgar Filing: NEOPROBE CORP - Form 10KSB

- o 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
- o 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.

Compensation Agreements With Other Named Executives

Carl M. Bosch

Employment Agreement. Carl Bosch is employed under a twenty-four month employment agreement effective January 1, 2005. The employment agreement provides for an annual base salary of \$149,000.

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. Mr. Bosch was paid a bonus of \$6,000 relating to fiscal year 2004.

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

- o 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);
- o the term of Mr. Bosch's employment agreement expires; or

55

- o 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 \$298,000 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:

- o 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

securities with voting power in the next meeting of holders of voting securities to elect the directors;

- o 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;
- o 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
- o 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.

Mr. Bosch will be paid a severance amount of \$149,000 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.

Rodger A. Brown

Employment Agreement. Rodger Brown is employed under a twenty-four month employment agreement effective January 1, 2005. The employment agreement provides for an annual base salary of \$124,000.

The terms of Mr. Brown's employment agreement are substantially identical to Mr. Bosch's employment agreement except that Mr. Brown would be paid \$248,000 if terminated due to a change of control and \$124,000 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. Mr. Brown was paid a bonus of \$2,500 relating to fiscal year 2004.

Brent L. Larson

Employment Agreement. Brent Larson is employed under a twenty-four month employment agreement effective January 1, 2005. The employment agreement provides for an annual base salary of \$149,000.

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. Mr. Larson was paid a bonus of \$6,000

Edgar Filing: NEOPROBE CORP - Form 10KSB

relating to fiscal year 2004.

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, 2004, 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)	
	-----	-----	-----
Equity compensation plans approved by security holders	4,857,641	\$ 0.59	
Equity compensation plans not approved by security holders	--	--	
	-----	-----	-----
Total	4,857,641	\$ 0.59	
	=====	=====	=====

57

Security Ownership of Principal Stockholders, Directors, Nominees and Executive Officers and Related Stockholder Matters

The following table sets forth, as of March 15, 2005, certain information with respect to the beneficial ownership of shares of our 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 or nominee for director of our Company, (iii) each of the Named Executives (see "Executive Compensation - Summary Compensation Table"), and (iv) our directors and executive officers as a group.

	Number of Shares Beneficially Owned(*)	Percent of Class(**)
Beneficial Owner	-----	-----
-----	-----	-----

Edgar Filing: NEOPROBE CORP - Form 10KSB

Carl J. Aschinger, Jr.	63,000 (a)	(q)
Reuven Avital	224,256 (b)	(q)
Anthony K. Blair	50,000 (c)	(q)
Kirby I. Bland	60,000 (d)	(q)
Carl M. Bosch	324,291 (e)	(q)
Rodger A. Brown	234,501 (f)	(q)
David C. Bupp	2,294,646 (g)	3.8%
Nancy E. Katz	117,400 (h)	(q)
Julius R. Krevans	302,000 (i)	(q)
Brent L. Larson	417,305 (j)	(q)
Fred B. Miller	136,000 (k)	(q)
Douglas L. Rash	16,667 (l)	(q)
J. Frank Whitley, Jr.	176,000 (m)	(q)
All directors and officers as a group (11 persons)	4,416,066 (n)	7.1%
Dan Purjes, et al. 830 Third Avenue, 14th Floor New York, NY 10022	3,913,044 (o)	6.6%
Great Point Partners, L.P. 2 Pickwick Plaza, Suite 450 Greenwich, CT 06830	30,000,000 (p)	33.9%

- (*) 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 December 20, 2004, plus the number of shares the person has the right to acquire within 60 days of December 20, 2004.
- (a) This amount includes 40,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 40,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (b) This amount consists of 139,526 shares of our common stock owned by Mittai Investments Ltd. (Mittai), an investment fund under the management and control of Mr. Avital, and 85,000 shares issuable upon exercise of options which are exercisable within 60 days but does not include 40,000 shares issuable upon exercise of options which are not exercisable within 60 days. The shares held by Mittai were obtained through a distribution of 2,785,123 shares previously held by Ma'Aragim Enterprise Ltd. (Ma'Aragim) another investment fund under the management and control of Mr. Avital. On February 28, 2005, Ma'Aragim distributed its shares to the partners in the fund. Mr. Avital is not an affiliate of the other fund to which the remaining 2,645,867 shares were distributed. Of the 2,785,123 shares previously held by Ma'Aragim, 2,286,712 were acquired in exchange for surrendering its shares in Cardiosonix Ltd. on December 31, 2001, in connection with our acquisition of Cardiosonix, and 498,411 were acquired by Ma'Aragim based on the satisfaction of certain developmental milestones on December 30, 2002, associated with our acquisition of Cardiosonix.
- (c) This amount does not include 90,000 shares issuable upon exercise of options which are not exercisable within 60 days.

- (d) This amount includes 60,000 shares issuable upon exercise of options which are exercisable within 60 days but does not include 50,000 shares issuable

Edgar Filing: NEOPROBE CORP - Form 10KSB

- upon exercise of options which are not exercisable within 60 days.
- (e) This amount includes 240,001 shares issuable upon exercise of options which are exercisable within 60 days and 44,290 shares in Mr. Bosch's account in the 401(k) Plan, but does not include 169,999 shares issuable upon exercise of options which are not exercisable within 60 days.
 - (f) This amount includes 234,501 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 159,999 shares issuable upon exercise of options which are not exercisable within 60 days.
 - (g) This amount includes 703,334 shares issuable upon exercise of options which are exercisable within 60 days, 875,000 warrants which are exercisable within 60 days, a promissory note convertible into 250,000 shares of our common stock, 50,875 shares that are held by Mr. Bupp's wife for which he disclaims beneficial ownership and 64,937 shares in Mr. Bupp's account in the 401(k) Plan, but it does not include 506,666 shares issuable upon exercise of options which are not exercisable within 60 days.
 - (h) This amount includes 117,400 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 40,000 shares issuable upon the exercise of options which are not exercisable within 60 days.
 - (i) This amount includes 302,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 60,000 shares issuable upon exercise of options which are not exercisable within 60 days.
 - (j) This amount includes 297,201 shares issuable upon exercise of options which are exercisable within 60 days and 44,604 shares in Mr. Larson's account in the 401(k) Plan, but it does not include 169,999 shares issuable upon exercise of options which are not exercisable within 60 days.
 - (k) This amount includes 125,000 shares issuable upon exercise of options which are exercisable within 60 days and 11,000 shares held by Mr. Miller's wife for which he disclaims beneficial ownership, but does not include 60,000 shares issuable upon the exercise of options which are not exercisable within 60 days.
 - (l) This amount includes 16,667 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 73,333 shares issuable upon exercise of options which are not exercisable within 60 days.
 - (m) This amount includes 175,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 40,000 shares issuable upon exercise of options which are not exercisable within 60 days.
 - (n) This amount includes 2,391,704 shares issuable upon exercise of options which are exercisable within 60 days and 153,831 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 1,499,996 shares issuable upon the exercise of options which are not exercisable within 60 days. The Company itself is the trustee of the Neoprobe 401(k) Plan and may, as such, share investment power over common stock held in such plan. The trustee disclaims any beneficial ownership of shares held by the 401(k) Plan. The 401(k) Plan holds an aggregate total of 310,333 shares of common stock.
 - (o) This amount consists of 434,783 shares owned by MFW Associates, 217,391 warrants held by MFW associates which are exercisable within 60 days, 869,565 shares owned collectively by Dan & Edna Purjes, 434,783 warrants held collectively by Dan & Edna Purjes which are exercisable within 60 days, 217,391 shares owned by Y Securities Management, Ltd., 108,696 warrants held by Y Securities Management, Ltd. which are exercisable within 60 days, 217,391 shares owned by the Purjes Foundation, 108,696 warrants held by the Purjes Foundation which are exercisable within 60 days, 869,565 shares owned by Dan Purjes IRA and 434,783 warrants held by Dan Purjes IRA which are exercisable within 60 days (collectively, Dan Purjes, et al.). 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 a registration statement and represents the best information available to us at the time of this filing.
 - (p) This amount includes 11,000,000 shares issuable upon conversion of promissory notes in the original principal amount of \$4,400,000 held by Biomedical Value Fund, L.P. (BVF) that are convertible within 60 days,

Edgar Filing: NEOPROBE CORP - Form 10KSB

9,000,000 shares issuable upon conversion of promissory notes in the original principal amount of \$3,600,000 held by Biomedical Offshore Value Fund, LTD. (BOVF) that are convertible within 60 days, 5,500,000 warrants held by BVF that are exercisable within 60 days and 4,500,000 warrants held by BOVF that are exercisable within 60 days. BVF and BOVF are investment funds managed by Great Point Partners, LLP.

(q) 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.

59

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 December 31, 1998 Form 10-K).
10.3	Amendment Number 2 to the Rights Agreement between the Company and Continental Stock Transfer & Trust Company dated December 31, 2004.*
10.4	Common Stock Purchase Agreement between the Company and Fusion Capital Fund II, LLC dated November 19, 2001 (incorporated by reference to Exhibit 99(b) of the Company's December 3, 2001 Form 8-K).
10.5	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).

Edgar Filing: NEOPROBE CORP - Form 10KSB

- 10.6 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).
 - 10.7 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 Employment Agreement between the Company and David C. Bupp, dated January 1, 2004 (incorporated by reference to Exhibit 10.12 to the Company's December 31, 2003 Form 10-KSB).
 - 10.9 Employment Agreement between the Company and Carl M. Bosch, dated January 1, 2005 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 5, 2005. This is one of five substantially identical employment agreements. A schedule identifying the other agreements and setting forth the material details in which such agreements differ from the one that is filed herewith is attached as Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 5, 2005).
 - 10.10 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).
- 60
- 10.11 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).
 - 10.12 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).
 - 10.13 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).
 - 10.14 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).
 - 10.15 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).
 - 10.16 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

been filed separately with the Commission), (incorporated by reference to Exhibit 10.4.49 to the Company's December 31, 2001 Form 10-KSB).

- 10.17 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).*
- 10.18 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).
- 10.19 8.5% Senior Note dated April 2, 2003 between the Company and David C. Bupp, as amended March 8, 2004 (incorporated by reference to Exhibit 10.24 to the Company's December 31, 2003 Form 10-KSB).
- 10.20 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).
- 10.21 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).
- 10.22 Security Agreement dated April 2, 2003 between the Company, David C. Bupp and Donald E. Garlikov (Incorporated by reference to Exhibit 99(f) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.23 Warrant to Purchase Common Stock of Neoprobe Corporation dated March 8, 2004 between the Company and David C. Bupp (incorporated by reference to Exhibit 10.28 to the Company's December 31, 2003 Form 10-KSB).
- 10.24 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).
- 10.25 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(h) to the Company's Current Report on Form 8-K filed April 2, 2003).
- 10.26 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).
- 10.27 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).

Edgar Filing: NEOPROBE CORP - Form 10KSB

- 10.28 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).
- 10.29 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).
- 10.30 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).
- 10.31 Securities Purchase Agreement, dated as of December 13, 2004, among Neoprobe Corporation, Biomedical Value Fund, L.P., Biomedical Offshore Value Fund, Ltd. and David C. Bupp. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 16, 2004).
- 10.32 Form of Neoprobe Corporation 8% Series A Convertible Promissory Note. (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 16, 2004. This is the form of three substantially identical agreements. A schedule identifying the other agreements and setting forth the material details in which such agreements differ from the one filed as Exhibit 10.4 to the Company's Current Report on Form 8-K filed December 16, 2004).
- 10.33 Form of Series T Neoprobe Corporation Common Stock Purchase Warrant (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed December 16, 2004.. This is the form of three substantially identical agreements. A schedule identifying the other agreements and setting forth the material details in which such agreements differ from the one that is filed herewith is attached as Exhibit 10.4 to the Company's Current Report on Form 8-K filed December 16, 2004).
- 10.34 Security Agreement, dated as of December 13, 2004, made by Neoprobe Corporation in favor of Biomedical Value Fund, L.P., Biomedical Offshore Value Fund, Ltd. and David C. Bupp. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 16, 2004).
- 10.35 Form of Series U Warrant Agreement dated December 13, 2004 between the Company and the placement agents for the Series A Convertible Promissory Notes and Series T Warrants. (This is the form of six substantially identical agreements. A schedule identifying the other agreements and setting forth the material details in which such agreements differ from the one filed herewith is attached as Exhibit 10.36.)*
- 10.36 Schedule identifying omitted documents.*
- 23.1 Consent of KPMG LLP.*
- 24.1 Powers of Attorney.*
- 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 2004 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 \$149,500 (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 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).

Audit-Related Fees. The aggregate fees billed by KPMG LLP for audit-related services rendered for the company for the 2004 fiscal year were \$22,840. The aggregate fees billed KPMG LLP for audit-related services rendered for the company and its subsidiaries for the 2003 fiscal year were \$11,500. 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 2004 fiscal year were \$6,500. The aggregate fees billed by KPMG LLP for tax-related services rendered for the company and its subsidiaries for the 2003 fiscal year were \$6,525. The tax-related services 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 2004 fiscal year and \$0 for the 2003 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

by the undersigned, thereunto duly authorized.

Dated: March 31, 2005

NEOPROBE CORPORATION
(the Company)

By: /s/ David C. Bupp

David C. Bupp, President and
Chief Executive Officer

Signature -----	Title -----	Date ----
/s/David C. Bupp ----- David C. Bupp	Director, President and Chief Executive Officer (principal executive officer)	March 23, 2005
/s/ Brent L. Larson* ----- Brent L. Larson	Vice President, Finance and Chief Financial Officer (principal financial officer)	March 15, 2005
/s/ Carl J. Aschinger, Jr.* ----- Carl J. Aschinger, Jr.	Director	March 24, 2005
/s/ Reuven Avital* ----- Reuven Avital	Director	March 17, 2005
/s/ Kirby I. Bland* ----- Kirby I. Bland	Director	March 23, 2005
/s/ Nancy E. Katz* ----- Nancy E. Katz	Director	March 28, 2005
/s/ Julius R. Krevans* ----- Julius R. Krevans	Chairman, Director	March 24, 2005
/s/ Fred B. Miller* ----- Fred B. Miller	Director	March 17, 2005
/s/ J. Frank Whitley, Jr.* ----- J. Frank Whitley, Jr.	Director	March 24, 2005

Edgar Filing: NEOPROBE CORP - Form 10KSB

*By: /s/ David C. Bupp

David C. Bupp, Attorney-in-fact

64

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

NEOPROBE CORPORATION

FORM 10-KSB ANNUAL REPORT
FOR THE FISCAL YEARS ENDED:
DECEMBER 31, 2004 AND 2003

FINANCIAL STATEMENTS

NEOPROBE CORPORATION and SUBSIDIARY

Index to Financial Statements

Consolidated Financial Statements of Neoprobe Corporation

Report of Independent Registered Public Accounting Firm

F-2

Edgar Filing: NEOPROBE CORP - Form 10KSB

Consolidated Balance Sheets as of December 31, 2004 and December 31, 2003	F-3
Consolidated Statements of Operations for the years ended December 31, 2004 and December 31, 2003	F-5
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2004 and December 31, 2003	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2004 and December 31, 2003	F-7
Notes to the Consolidated Financial Statements	F-8

F-1

Report of Independent Registered Public Accounting Firm

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, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2004. 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Neoprobe Corporation and subsidiary as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Columbus, Ohio
March 31, 2005

F-2

Neoprobe Corporation and Subsidiary
Consolidated Balance Sheets

Edgar Filing: NEOPROBE CORP - Form 10KSB

December 31, 2004 and 2003

ASSETS	2004

Current assets:	
Cash and cash equivalents	\$ 9,842,658
Accounts receivable, net	411,856
Inventory	855,022
Prepaid expenses and other	327,408

Total current assets	11,436,944

Property and equipment	2,341,785
Less accumulated depreciation and amortization	2,003,942

	337,843

Patents and trademarks	3,155,334
Non-compete agreements	584,516
Acquired technology	237,271

	3,977,121
Less accumulated amortization	1,458,012

	2,519,109

Other assets	1,071,999

Total assets	\$ 15,365,895
	=====

Continued

F-3

Neoprobe Corporation and Subsidiary
Consolidated Balance Sheets, continued

LIABILITIES AND STOCKHOLDERS' EQUITY	2004

Current liabilities:	
Notes payable to finance companies	\$ 242,72
Accounts payable	198,91

Edgar Filing: NEOPROBE CORP - Form 10KSB

Accrued liabilities and other		378,24
Capital lease obligations, current		13,86
Deferred revenue, current		176,19

Total current liabilities		1,009,93

Capital lease obligations		30,29
Deferred revenue		57,59
Notes payable to CEO, net of discounts of \$32,204 and \$12,702		67,79
Notes payable to investor, net of discounts of \$2,576,302 and \$32,496		5,423,69
Liability related to warrants to purchase common stock		2,560,30
Other liabilities		52,44

Total liabilities		9,202,06

Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$.001 par value; 5,000,000 shares authorized at December 31, 2004 and 2003; none issued and outstanding (500,000 shares designated as Series A, \$.001 par value, at December 31, 2004 and 2003; none outstanding)		-
Common stock; \$.001 par value; 100,000,000 shares authorized, 58,378,143 shares issued and outstanding at December 31, 2004; 75,000,000 authorized, 51,520,723 shares issued and outstanding at December 31, 2003		58,37
Additional paid-in capital		132,123,60
Accumulated deficit		(126,018,15)

Total stockholders' equity		6,163,83

Total liabilities and stockholders' equity		\$ 15,365,89
		=====

See accompanying notes to consolidated financial statements.

F-4

Neoprobe Corporation and Subsidiary
Consolidated Statements of Operations

	Years Ended December 31,	
	2004	2003
	-----	-----
Revenues:		
Net sales	\$ 5,352,640	\$ 5,564,275
License and other revenue	600,000	945,633
	-----	-----
Total revenues	5,952,640	6,509,908
	-----	-----

Edgar Filing: NEOPROBE CORP - Form 10KSB

Cost of goods sold	2,344,925	3,124,978
	-----	-----
Gross profit	3,607,715	3,384,930
	-----	-----
Operating expenses:		
Research and development	2,453,755	1,893,520
Selling, general and administrative	3,153,059	3,102,535
	-----	-----
Total operating expenses	5,606,814	4,996,055
	-----	-----
Loss from operations	(1,999,099)	(1,611,125)
	-----	-----
Other income (expense):		
Interest income	28,869	9,423
Interest expense	(334,196)	(186,912)
Increase in warrant liability	(1,245,307)	--
Other	8,711	(10,381)
	-----	-----
Total other expenses	(1,541,923)	(187,870)
	-----	-----
Net loss	\$ (3,541,022)	\$ (1,798,995)
	=====	=====
Net loss per common share:		
Basic	\$ (0.06)	\$ (0.04)
Diluted	\$ (0.06)	\$ (0.04)
Weighted average shares outstanding:		
Basic	56,763,710	40,337,679
Diluted	56,763,710	40,337,679

See accompanying notes to consolidated financial statements.

F-5

Neoprobe Corporation and Subsidiary
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in Capital
	Shares	Amount	
	-----	-----	-----
Balance, December 31, 2002	36,502,183	\$ 36,502	\$ 124,601,770
Issued contingent stock related to 2001 acquisition of subsidiary	2,085,826	2,086	285,967
Removed restrictions on stock issued to executives	--	--	39,990
Issued warrants in connection with issuance of notes payable to CEO and investor	--	--	72,374

Edgar Filing: NEOPROBE CORP - Form 10KSB

Effect of beneficial conversion feature of note payable to investor	--	--	40,620
Issued stock to 401(k) plan at \$0.26	100,327	100	25,852
Issued stock in connection with stock purchase agreement	480,331	481	143,317
Issued stock and warrants in connection with private placement	12,173,914	12,174	2,497,026
Issued stock and warrants as fees to investment banking firms	178,142	178	56,895
Paid offering costs related to issuance of stock and warrants	--	--	(79,256)
Net loss	--	--	--
	-----	-----	-----
Balance, December 31, 2003	51,520,723	51,521	127,684,555
Issued stock upon conversion of note payable to investor	1,098,851	1,099	250,748
Issued warrants in exchange for extension of note payable to CEO	--	--	171,801
Issued stock upon exercise of warrants	3,251,354	3,251	874,488
Issued stock in connection with stock purchase agreement	2,416,129	2,416	1,468,918
Issued stock options to consultants	--	--	172,736
Effect of beneficial conversion feature of convertible promissory notes	--	--	1,315,000
Issued warrants as fees to investment banking firms	--	--	208,014
Issued stock to 401(k) plan at \$0.16	91,086	91	14,402
Paid offering costs related to issuance of stock and warrants	--	--	(37,057)
Net loss	--	--	--
	-----	-----	-----
Balance, December 31, 2004	58,378,143	\$ 58,378	\$ 132,123,605
	=====	=====	=====

See accompanying notes to consolidated financial statements.

F-6

Neoprobe Corporation and Subsidiary
Consolidated Statements of Cash Flows

	Years Ended December	
	2004	2003
	-----	-----
Cash flows from operating activities:		
Net loss	\$ (3,541,022)	\$ (1,700,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	154,703	200,000
Amortization of intangible assets	434,728	400,000
Provision for bad debts	79,718	0
Net loss on disposal and abandonment of assets	11,467	0

Edgar Filing: NEOPROBE CORP - Form 10KSB

Amortization of debt discount and offering costs	266,580	
Increase in warrant liability	1,245,307	
Stock options granted for research and development	172,736	
Other	15,551	1
Change in operating assets and liabilities:		
Accounts receivable	616,226	(4
Inventory	131,532	1
Prepaid expenses and other assets	169,001	4
Accounts payable	(26,120)	(2
Accrued liabilities and other liabilities	166,026	(3
Deferred revenue	(721,804)	(6
	-----	-----
Net cash used in operating activities	(825,371)	(1,8
	-----	-----
Cash flows from investing activities:		
Purchases of property and equipment	(87,923)	(
Proceeds from sales of property and equipment	2,960	(
Patent and trademark costs	(25,779)	(
	-----	-----
Net cash used in investing activities	(110,742)	(1
	-----	-----
Cash flows from financing activities:		
Proceeds from issuance of common stock	2,349,073	2,9
Payment of offering costs	(37,057)	(3
Proceeds from notes payable	8,100,000	5
Payment of debt issuance costs	(729,978)	(
Payment of notes payable	(476,125)	(2
Payments under capital leases	(15,902)	(
	-----	-----
Net cash provided by financing activities	9,190,011	2,8
	-----	-----
Net increase in cash and cash equivalents	8,253,898	8
Cash and cash equivalents, beginning of year	1,588,760	7
	-----	-----
Cash and cash equivalents, end of year	\$ 9,842,658	\$ 1,5
	=====	=====

See accompanying notes to consolidated financial statements.

F-7

Notes to the Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies:

- a. Organization and Nature of Operations: Neoprobe Corporation (Neoprobe, the company, 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 physicians. We currently manufacture two lines of

Edgar Filing: NEOPROBE CORP - Form 10KSB

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, 2004 and 2003, 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) CR, is intended to be used to help surgeons locate cancerous tissue during colorectal cancer surgeries. The second, Lymphoseek™, 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 cleared for marketing 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, 2004 and 2003, the carrying values of these instruments approximate fair value.
 - (3) Notes payable to CEO: The fair value of our debt is presented as the face amount of the notes less the unamortized discounts related to the value of the beneficial conversion features and the estimated fair value of the warrants to purchase common stock issued in connection with the notes. At December 31, 2004, the fair value of the note payable to our CEO is approximately \$75,000, as determined by a third-party valuation expert. At December 31, 2003, the carrying value of the note payable to our CEO approximates fair value.
 - (4) Notes payable to outside investors: The fair value of our debt is presented as the face amount of the notes less the unamortized discounts related to the value of the beneficial conversion features and the estimated fair value of the warrants to purchase common stock issued in connection with the notes. At December 31,

Edgar Filing: NEOPROBE CORP - Form 10KSB

2004, the fair value of the note payable to outside investors is approximately \$6.0 million, as determined by a third-party valuation expert. At December 31, 2003, the carrying value of the note payable to an outside investor approximates fair value.

F-8

Notes to the Consolidated Financial Statements

- d. **Cash and Cash Equivalents:** There were no cash equivalents at December 31, 2004 or 2003. As of December 31, 2004 and 2003, \$19,000 and \$8,000, respectively, was restricted to secure a bank guarantee related to a sub-lease agreement for Cardiosonix' office space.
- 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. The components of net inventory at December 31, 2004 and 2003 are as follows:

	2004	2003
Materials and component parts	\$ 486,323	\$ 747,788
Finished goods	368,699	260,538
	\$ 855,022	\$ 1,008,326

During 2004 and 2003, we wrote off \$107,000 and \$70,000, respectively, of excess and obsolete materials, primarily due to design changes of our Quantix(R) product line.

- 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 \$56,000 and \$80,000 of equipment under capital leases with accumulated amortization of \$14,000 and \$48,000 at December 31, 2004 and 2003, respectively. During 2004 and 2003, we recorded losses of \$4,000 and \$20,000, respectively, on the disposal of property and equipment.

The major classes of property and equipment are as follows:

	Useful Life	2004
Production machinery and equipment	5 years	\$ 1,060,610
Other machinery and equipment, primarily computers and research equipment	2 - 5 years	663,772
Furniture and fixtures	7 years	360,663
Leasehold improvements	Life of Lease	134,856
Software	3 years	121,884

- 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.

F-9

Notes to the Consolidated Financial Statements

The major classes of intangible assets are as follows:

	December 31, 2004		Dec
	Gross Carrying Amount	Accumulated Amortization	Gross Carry Amount
Patents and trademarks	\$ 3,155,334	\$ 915,571	\$ 3,156,
Non-compete agreements	584,516	440,005	584,
Acquired technology	237,271	102,436	237,
Total	\$ 3,977,121	\$ 1,458,012	\$ 3,977,

During 2004 and 2003, we recorded general and administrative expenses of \$442,000 and \$459,000, respectively, of intangible asset amortization expense. Of those amounts, \$7,000 and \$30,000, 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 12/31/2005	\$ 423,524
For the year ended 12/31/2006	267,576
For the year ended 12/31/2007	235,237
For the year ended 12/31/2008	205,170

Edgar Filing: NEOPROBE CORP - Form 10KSB

For the year ended 12/31/2009

170,940

h. Other Assets

Other assets consist primarily of deferred debt issuance costs. We defer costs associated with the issuance of notes payable and amortize those costs over the period of the notes using the effective interest method. In 2004 and 2003, we incurred \$938,000 and \$42,000, respectively, of debt issuance costs related to notes payable. Of the debt issuance costs incurred in 2004, \$208,000 was non-cash in nature. See Note 6.

i. 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.

F-10

Notes to the Consolidated Financial Statements

- (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.
- (3) **Service Revenue:** We derive revenues from the repair and service of our medical devices that are in use beyond the term of the original 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.

Edgar Filing: NEOPROBE CORP - Form 10KSB

- (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 licensed to us, we incur no significant cost associated with the recognition of this revenue. The license revenue was fully recognized as of September 30, 2004.
- j. Research and Development Costs: All costs related to research and development are expensed as incurred.
- k. 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.
- l. Stock Option Plans: At December 31, 2004, 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 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 during the first quarter of 2003.

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 2004 and 2003, respectively: average risk-free interest rates of 3.0% and 2.6%; volatility of 127% for 2004 and 146% for 2003; and no dividend rate for any year. The weighted average fair value of options granted in 2004 and 2003 was \$0.39 and \$0.16, respectively.

F-11

Notes to the Consolidated Financial Statements

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:

Edgar Filing: NEOPROBE CORP - Form 10KSB

	Years Ended Decem
	----- 2004 -----
Net loss, as reported	\$ (3,541,022)
Add: Total stock-based employee compensation expense included in reported net loss	--
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(304,266)

Pro forma net loss	\$ (3,845,288) =====
Loss per common share:	
As reported (basic and diluted)	\$ (0.06)
Pro forma (basic and diluted)	\$ (0.07)

- m. **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 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. During 2004 and 2003, we issued 250,000 and 80,000 options, respectively, to non-employee consultants. During 2004, we recognized \$173,000 of research and development expense related to options granted to consultants.
- n. **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.
- o. **Comprehensive Income (Loss):** We had no accumulated other comprehensive income (loss) activity during the years ended December 31, 2004 and 2003.
- p. **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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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.

F-12

Notes to the Consolidated Financial Statements

2. Earnings Per Share:

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.

	Year Ended December 31, 2004		Year December
	Basic Earnings Per Share	Diluted Earnings Per Share	Basic Earnings Per Share
Outstanding shares	58,378,143	58,378,143	51,520,723
Effect of weighting changes in outstanding shares	(1,484,433)	(1,484,433)	(11,053,044)
Contingently issuable shares	(130,000)	(130,000)	(130,000)
	56,763,710	56,763,710	40,337,679
Adjusted shares	56,763,710	56,763,710	40,337,679

There is no difference in basic and diluted loss per share related to 2004 or 2003. The net loss per common share for 2004 and 2003 excludes the number of common shares issuable upon exercise of outstanding stock options, warrants, and convertible debt into our common stock since such inclusion would be anti-dilutive.

3. Accounts Receivable and Concentrations of Credit Risk:

Accounts receivable at December 31, 2004 and 2003, net of allowance for doubtful accounts of \$2,000 and \$46,000, respectively, consist of the following:

	2004
Trade	\$ 403,674
Other	8,182
	\$ 411,856
	\$ 411,856

Edgar Filing: NEOPROBE CORP - Form 10KSB

At December 31, 2004 and 2003, approximately 88% and 85%, 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.

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, 2004 and 2003 is as follows:

	2004

Allowance for doubtful accounts at beginning of year	\$ 46,000
Provision for bad debts	8,718
Write-offs charged against the allowance	(53,024)

Allowance for doubtful accounts at end of year	\$ 1,694
	=====

F-13

Notes to the Consolidated Financial Statements

4. Accrued Liabilities and Accounts Payable:

Accrued liabilities at December 31, 2004 and 2003 consist of the following:

	2004

Contracted services and other	\$ 241,608
Warranty reserve	66,000
Compensation	56,547
Inventory purchases	14,092

	\$ 378,247
	=====

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.

The activity in the warranty reserve account for the years ended December 31, 2004 and 2003 is as follows:

Edgar Filing: NEOPROBE CORP - Form 10KSB

	2004
Warranty reserve, at beginning of year	\$ 53,000
Provision for warranty claims and changes in reserve for warranties	20,849
Payments charged against the reserve	(7,849)
Warranty reserve, at end of year	\$ 66,000

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 to Mr. Bupp in the principal amount of \$250,000. The note was secured by general assets of the company, excluding accounts receivable. In addition, we issued Mr. Bupp 375,000 warrants to purchase our common stock at an exercise price of \$0.13 per share, expiring in April 2008. The per share 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. The note bore interest at 8.5% per annum, payable monthly, and the note was originally due on June 30, 2004. On March 8, 2004, at the request of the Board of Directors, Mr. Bupp agreed to extend the due date of the note from June 30, 2004 to June 30, 2005. In exchange for extending the due date of the note, we issued Mr. Bupp an additional 375,000 warrants to purchase our common stock at an exercise price of \$0.50 per share, expiring in March 2009. 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. The total estimated fair values for the warrants issued to Mr. Bupp in April 2003 and March 2004 were \$31,755 and \$171,801, respectively. These amounts were recorded as discounts on the note and were amortized over the period of the note. On December 13, 2004, we paid the balance of the note to Mr. Bupp. The discount remaining at the date of payment totaling \$74,230 was recorded as interest expense.

F-14

Notes to the Consolidated Financial Statements

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 to the investor in the principal amount of \$250,000. The note was secured by general assets of the company, excluding accounts receivable. In addition, we issued the investor 500,000 warrants to purchase our common stock at an exercise price of \$0.13 per share, expiring in April 2008. The per share 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. The total estimated fair value for the warrants issued to the outside investor was \$40,620. Under the terms of the agreement, 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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. 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 estimated fair value of the warrants and the intrinsic value of the conversion feature were recorded as discounts on the note and were amortized over the term of the note. 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 the 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. The discount remaining at conversion totaling \$27,604 was recorded as interest expense.

In December 2004, we completed a private placement of convertible promissory notes in an aggregate principal amount of \$8.1 million with Biomedical Value Fund, L.P., Biomedical Offshore Value Fund, Ltd. and David C. Bupp (our President and CEO). Biomedical Value Fund, L.P. and Biomedical Offshore Value Fund, Ltd. are funds managed by Great Point Partners, LLC. The notes bear interest at 8% per annum, payable quarterly on each March 31, June 30, September 30 and December 31 of each year, and are freely convertible into shares of our common stock at a price of \$0.40 per share. Neoprobe may force conversion of the notes prior to their stated maturity under certain circumstances. All of our material assets, except the intellectual property associated with our Lymphoseek and RIGS products under development, have been pledged as collateral for these notes.

In addition to the security interest in our assets, the notes carry substantial covenants that impose significant requirements on us, including, among others, requirements that: we pay all principal, interest and other charges on the notes when due; we use the proceeds from the sale of the notes only for permitted purposes such as Lymphoseek development and general corporate purposes; we nominate and recommend for election as a director a person designated by the holders of the notes; we keep reserved out of our authorized shares of common stock sufficient shares to satisfy our obligation to issue shares on conversion of the notes and the exercise of the warrants issued in connection with the sale of the notes; we achieve annual revenues on a consolidated basis of at least \$5.4 million in 2005, \$6.5 million in 2006, and \$9.0 million in each year thereafter; we maintain minimum cash balances of \$4.5 million at the end of the first six months of 2005, \$4.0 million at the end of the second six months of 2005, and \$3.5 million at the end of each six-month period thereafter; and we indemnify the purchasers of the notes against certain liabilities. Additionally, with certain exceptions, the notes prohibit us from: amending our organizational or governing agreements and documents, entering into any merger or consolidation, dissolving the company or liquidating its assets, or acquiring all or any substantial part of the business or assets of any other person; engaging in transactions with any affiliate; entering into any agreement inconsistent with our obligations under the Notes and related agreements; incurring any indebtedness, capital leases, or contingent obligations outside the ordinary course of business; granting or permitting liens against or security interests in our assets; making any material dispositions of our assets outside the ordinary course of business; declaring or paying any dividends or making any other restricted payments; or making any loans to or investments in other persons outside of the ordinary course of business.

Notes to the Consolidated Financial Statements

As part of this transaction, we issued the investors 10,125,000 Series T warrants to purchase our common stock at an exercise price of \$0.46, expiring in December 2009. The fair value of the warrants issued to the investors was \$1,315,000 on the date of issuance and was determined by a third-party valuation expert using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.4%, volatility of 50% and no expected dividend rate. In connection with this financing, we also issued 1,600,000 warrants to purchase our common stock to the placement agents, containing substantially the same terms as the warrants issued to the investors. The fair value of the warrants issued to the placement agents was \$208,014 using the Black-Scholes option pricing model with the same assumptions used to determine the fair value of the warrants issued to the investors. The intrinsic value of the conversion feature of the notes was estimated at \$1,315,000 based on the effective conversion price at the date of issuance. The fair value of the warrants issued to the investors and the intrinsic value of the conversion feature were recorded as discounts on the note and will be amortized over the term of the note using an effective interest rate of 19.8%. The fair value of the warrants issued to the placement agents was recorded as a deferred debt issuance cost and will be amortized over the term of the note. See Note 1(h). If we issue equity at prices below the conversion rate for the promissory notes (and for the warrants below the exercise price), then we would be required to reset the exercise and conversion prices for these securities. This provision results in a contingent beneficial conversion feature that may require us to estimate an additional debt discount if a reset occurs.

Current generally accepted accounting principles also require that the warrants issued in connection with the placement be classified as a liability due to penalty provisions contained in the securities purchase agreement. We would be required to pay a penalty of 0.0667% of the total debt amount if we fail to meet certain registration deadlines, or if we are suspended for more than 30 days. As a liability, the warrants are considered a derivative instrument that must be periodically "marked to market" on our balance sheet. We estimated the fair value of the warrants at December 31, 2004 using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.4%, volatility of 50% and no expected dividend rate. Because the value of our stock increased \$0.19 per share from \$0.40 per share at the closing date of the financing on December 14, 2004 to \$0.59 per share at December 31, 2004, our year end, the effect of marking the warrant liability to "market" resulted in an increase in the estimated fair value of the warrant liability of \$1.2 million which was recorded as non-cash expense during the fourth quarter of 2004. See Note 16(b).

7. Income Taxes:

As of December 31, 2004, our net deferred tax assets in the U.S. were approximately \$37.9 million. Approximately \$33.4 million of the deferred tax assets relate principally to net operating loss carryforwards of approximately \$91.4 million available to offset future federal taxable income, and net operating loss carryforwards of approximately \$41.2 million available to offset future state taxable income, if any, through 2024. An additional \$4.2 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 2024. The

Edgar Filing: NEOPROBE CORP - Form 10KSB

remaining \$310,000 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, 2004.

As of December 31, 2004, Cardiosonix had net deferred tax assets in Israel of approximately \$2.2 million, primarily related to net operating loss carryforwards of approximately \$6.1 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, 2004. 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.

F-16

Notes to the Consolidated Financial Statements

8. Equity:

- a. **Stock Options:** At December 31, 2004, 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. The Amended Plan was approved by the stockholders in 1994, and although options are still outstanding under this plan, the Amended Plan is considered expired and no new grants may be made from it. 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 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.

A summary of the status of stock options under our stock option plans as of December 31, 2004 and 2003, and changes during the years ended on

Edgar Filing: NEOPROBE CORP - Form 10KSB

those dates is presented below:

	2004		2003
	Options	Weighted Average Exercise Price	Options
Outstanding at beginning of year	2,931,308	\$ 0.56	2,317,725
Granted	2,278,000	\$ 0.41	1,030,000
Forfeited	(351,667)	\$ 0.30	(416,417)
Exercised	--	--	--
Outstanding at end of year	4,857,641	\$ 0.51	2,931,308

Of the options granted during 2004 and 2003, 250,000 and 80,000, respectively, were granted to non-employee consultants. All of these consultant options remain outstanding as of December 31, 2004. During 2004, we recognized \$173,000 of research and development expense related to options granted to consultants.

Included in outstanding options as of December 31, 2004, 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, 2004:

Range of Exercise Prices	Options Outstanding			Number of Exercisable Options as of December 31, 2004
	Number Outstanding as of December 31, 2004	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	
\$ 0.13 - \$ 0.30	1,361,668	9 years	\$ 0.23	
\$ 0.31 - \$ 0.41	1,237,500	8 years	\$ 0.39	
\$ 0.42 - \$ 0.50	1,503,000	7 years	\$ 0.47	
\$ 0.60 - \$ 5.63	755,473	5 years	\$ 1.29	
	4,857,641	8 years	\$ 0.51	2,931,308

Edgar Filing: NEOPROBE CORP - Form 10KSB

- 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, 2004, 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, 2004, there are 17.3 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from \$0.13 to \$0.75 per share with a weighted average exercise price per share of \$0.40.

The following table summarizes information about our outstanding warrants at December 31, 2004:

	Exercise Price	Number of Warrants	Expiration Date
	-----	-----	-----
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 Q	\$ 0.50	375,000	March 2009
Series R	\$ 0.28	2,952,176	October 2008
Series S	\$ 0.28	1,259,065	October 2008
Series T	\$ 0.46	10,125,000	December 2009
Series U	\$ 0.46	1,600,000	December 2009
	\$ 0.40	17,286,241	
		=====	

- d. **Common Stock Reserved:** Shares of authorized common stock have been reserved for the exercise of all options, warrants, and convertible debt 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 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 2004 and 2003, we sold Fusion a total of 2,350,000 and 473,869 shares of common stock and realized net proceeds of \$1,468,874 and \$143,693, respectively. We also issued Fusion 66,129 and 6,462 shares of common stock, respectively, for commitment fees related to the sales of our common stock to them during 2004 and 2003.

- f. Private Placement: 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. During 2004, 3,308,327 of these warrants were exercised and we realized net proceeds of \$871,398.

F-18

Notes to the Consolidated Financial Statements

During 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 upon 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 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.

9. Shareholder Rights Plan:

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 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 related to two gamma detection drugs. We also 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. Prior to 2004, gamma detection drugs and devices were reported as one segment. Certain 2003 amounts have been reclassified to conform to the 2004 presentation.

F-19

Notes to the Consolidated Financial Statements

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 (expenses), 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) 2004	Gamma Detection Drugs	Gamma Detection Devices	Blood Flow Devices
-----	-----	-----	-----
Net sales:			
United States(1)	\$ --	\$ 5,173	\$ --
International	--	91	89
License and other revenue	--	600	--
Research and development expenses	489	404	1,561
Selling, general and administrative expenses	--	--	--
Income (loss) from operations(2)	(489)	3,342	(1,699)

Edgar Filing: NEOPROBE CORP - Form 10KSB

Other expenses	--	--	--
Total assets, net of depreciation and amortization:			
United States	3	1,138	64
Cardiosonix Ltd.	--	--	2,899
Capital expenditures	--	12	22
2003			

Net sales			
United States(1)	\$ --	\$ 5,284	\$ --
International	--	35	245
License and other revenue	--	946	--
Research and development expenses	56	454	1,384
Selling, general and administrative expenses	--	--	--
Income (loss) from operations(2)	(56)	2,871	(1,323)
Other expenses	--	--	--
Total assets, net of depreciation and amortization:			
United States	--	1,728	146
Cardiosonix Ltd.	--	--	3,546
Capital expenditures	--	13	50

xxx

(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. 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. 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.

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. As of December 31, 2004, less than \$1,000 of royalties were accrued under the royalty agreement.

F-20

Notes to the Consolidated Financial Statements

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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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. Total purchases under the supply agreement were \$555,000 and \$138,000 for the years ended December 31, 2004 and 2003, respectively. We have issued purchase orders for \$227,000 of crystal modules for delivery of product through July 2005.

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 for the year ended December 31, 2003.

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/ORTM control unit and Quantix/NDTM 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. Total purchases under the product supply agreement were \$1.2 million for the year ended December 31, 2004. We have issued purchase orders for \$1.9 million of our products for delivery through December 2006.

- b. **Marketing and Distribution Agreement:** During 1999, we entered into a distribution agreement with EES covering our gamma detection devices used in ILM. The initial five-year term expired December 31, 2004, with options to extend for two successive two-year terms. 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. Under the agreement, we manufacture and sell our current line of ILM products exclusively to EES, who distributes the products globally, except in Japan. 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. 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

Edgar Filing: NEOPROBE CORP - Form 10KSB

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 recognized the license fee as revenue on a straight-line basis over the five-year initial term of the agreement, and the license fee was fully amortized into income as of the end of September 2004. 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.

F-21

Notes to the Consolidated Financial Statements

- 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). Through the end of 2004, Cardiosonix received a total \$775,000 in grants from 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 of its products, up to 300% of the total grants received, depending on the portion of manufacturing activity that takes place in Israel. 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, Cardiosonix may be required to refund the grant, in whole or in part, with or without interest, as the OCS determines. As we have notified the OCS of our intent to move parts of the manufacturing process outside of Israel, the total amount we will have to repay may be 150% to 300% of the amounts of the original grants. Through December 2004, we have paid the OCS a total of \$18,000 in royalties related to sales of products developed under this program. As of December 31, 2004, our obligation for royalties totaled \$2,000.

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 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 \$87,000 and \$29,000 in 2004 and 2003, respectively, and were recorded in research and development expenses.

UCSD has the right to terminate the agreement or change the nature of

Edgar Filing: NEOPROBE CORP - Form 10KSB

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

- d. **Employment Agreements:** We maintain employment agreements with four 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 \$1.6 million. The employment agreements also provide for severance, disability and death benefits. See Note 16(c).

Cardiosonix also maintains employment agreements with two 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. The maximum contingent liability under the agreements, excluding the potential royalty, is approximately \$55,000. See Note 10(b).

F-22

Notes to the Consolidated Financial Statements

12. Leases:

We lease certain office equipment under capital leases which expire from 2007 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 a new operating lease agreement for office space, which expires in September 2006. See Note 16 (e). In April 2002, Cardiosonix entered into an operating sublease agreement for office and parking space that expired in April 2004. In June 2004, Cardiosonix entered into a new operating sublease agreement for office space that expires in June 2005, with an option to extend the sublease through June 2006. In July 2004, Cardiosonix entered into a sublease agreement for parking space that expires in June 2005, and automatically renews until either party terminates the agreement. In addition, Cardiosonix leases two automobiles under three-year operating leases.

The future minimum lease payments for the years ending December 31 are as follows:

	Capital Leases	Operating Leases
	-----	-----
2005	\$ 18,308	\$ 145,562
2006	18,308	123,484
2007	9,502	99,757
2008	7,300	8,313
2009	--	--
	-----	-----
	53,418	\$ 377,116

Edgar Filing: NEOPROBE CORP - Form 10KSB

Less amount representing interest	9,258

Present value of net minimum lease payments	44,160
Less current portion	13,863

Capital lease obligations, excluding current portion	\$ 30,297
	=====

Total rental expense, net of sublease rental income of \$82,000 in 2003, was \$218,000 and \$238,000 for the years ended December 31, 2004 and 2003, 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 \$19,000 and \$14,000 during 2004 and 2003, respectively, related to common stock to be subsequently contributed to the plan.

14. Supplemental Disclosure for Statements of Cash Flows:

We paid interest aggregating \$52,000 and \$94,000 for the years ended December 31, 2004 and 2003, respectively. During 2004 and 2003, we purchased equipment under capital leases totaling \$27,000 and \$29,000, respectively. During 2004 and 2003, we transferred \$22,000 and \$14,000, respectively, in inventory to fixed assets related to the creation and maintenance of a pool of service loaner equipment. Also during 2004 and 2003, we prepaid \$277,000 and \$225,000, respectively, in insurance through the issuance of notes payable to finance companies with weighted average interest rates of 5% and 6%, respectively. The notes payable to finance companies issued in 2004 mature in August and October, 2005.

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.

F-23

Notes to the Consolidated Financial Statements

16. Subsequent Events:

- a. CIRA Biosciences, Inc.: In January 2005, we formed a new corporation, CIRA Biosciences, Inc. (CIRA Bio), to explore the development of patient-specific cellular therapies that have shown positive patient responses in a variety of clinical settings. CIRA Bio will combine our Activated Cellular Therapy technology for patient-specific oncology treatment with similar technology licensed from CIRA LLC, a privately held company, for treating viral and autoimmune diseases. Following the formation of CIRA Bio, Neoprobe owns approximately 90% of the outstanding shares of CIRA Bio with the remaining shares being held by the principals of CIRA LLC.

Edgar Filing: NEOPROBE CORP - Form 10KSB

- b. **Warrant Liability:** Subsequent to December 31, 2004, Neoprobe and the investors have confirmed in writing their intention that the penalty provisions which led to this accounting treatment were intended to apply only to the \$8.1 million principal balance of the promissory notes and underlying conversion shares and not to the warrant shares. As such, we intend to reclassify the estimated fair value of the warrant liability to additional paid-in capital during the first quarter of 2005. See Note 6.
- c. **Warrant Exercises:** During the first quarter of 2005, certain investors exercised a total of 206,865 warrants to purchase our common stock and we realized proceeds of \$57,922. See Note 8(c).
- d. **Employment Agreements:** Effective January 1, 2005, we entered into new employment agreements with five executive officers. The new agreements have substantially similar terms to the previous agreements, except that two of the officers would only be entitled to their current annual salaries in the event of termination of their employment resulting from a change in control of the company. The maximum contingent liability under these agreements in the event of termination is \$1.9 million. See Note 11(d).
- e. **Operating Lease:** In February 2005, we entered into a three-year operating lease agreement for additional office space. The additional lease payments total approximately \$22,000 per year. See Note 12.

F-24

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 registered public accounting firm. These data are qualified in their entirety by, and should be read in conjunction with, our Consolidated Financial Statements and Notes thereto included herein.

(Amounts in thousands, except per share data)	Years Ended December 31,			
	2004	2003	2002	2001
	-----	-----	-----	-----
Statement of Operations Data:				
Net sales	\$ 5,353	\$ 5,564	\$ 3,383	\$ 6,764
License and other revenue	600	946	1,538	1,428
Gross profit	3,608	3,385	2,570	3,802
Research and development expenses	2,454	1,894	2,324	948
Selling, general and administrative expenses	3,153	3,103	3,267	2,321
Acquired in-process research and development	--	--	(28)	885
	-----	-----	-----	-----
(Loss) income from operations	(1,999)	(1,611)	(2,993)	(352)
Other (expenses) income	(1,542)	(188)	29	370

Edgar Filing: NEOPROBE CORP - Form 10KSB

	-----	-----	-----	-----
Net (loss) income	\$ (3,541)	\$ (1,799)	\$ (2,964)	\$ 15
(Loss) income attributable to common stockholders	\$ (3,541) =====	\$ (1,799) =====	\$ (2,964) =====	\$ 15 =====
(Loss) Income per common share:				
Basic	\$ (0.06)	\$ (0.04)	\$ (0.08)	\$ 0.00
Diluted	\$ (0.06)	\$ (0.04)	\$ (0.08)	\$ 0.00
Shares used in computing (loss) income per common share: (1)				
Basic	56,764	40,338	36,045	25,899
Diluted	56,764	40,338	36,045	26,047
			As of December 31,	
	-----	-----	-----	-----
	2004	2003	2002	2001
	----	----	----	----
Balance Sheet Data:				
Total assets	\$ 15,366	\$ 7,385	\$ 7,080	\$ 11,329
Long-term obligations	8,192	585	1,169	1,981
Accumulated deficit	(126,018)	(122,477)	(120,678)	(117,714)

(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.