

NEOPROBE CORP  
Form 10-K  
March 30, 2009

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from to to

Commission file number 0-26520

NEOPROBE CORPORATION  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

31-1080091  
(I.R.S. Employer Identification No.)

425 Metro Place North, Suite 300, Dublin, Ohio  
(Address of principal executive offices)

43017-1367  
(Zip Code)

Registrant'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)

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or

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information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12-b-2 of the Act.) Yes  No

The aggregate market value of shares of common stock held by non-affiliates of the registrant on June 30, 2008 was \$46,998,239.

The number of shares of common stock outstanding on March 16, 2009 was 71,636,707.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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## 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:

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

In addition, in this report, we use words such as “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 report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

## PART I

### Item 1. Business

#### Development of the Business

Neoprobe Corporation (Neoprobe, the company or we) is a biomedical company that develops and commercializes innovative 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®) technology. In 1998, U.S. and European regulatory agencies completed an evaluation of the status of the regulatory pathway for our RIGS products, which coupled with our limited financial resources at the time, caused us to suspend our radiopharmaceutical development activities and refocus our operating strategy on our medical device business. After achieving profitability in the fourth quarter of 1999 following this retrenchment, we expanded our medical device offerings in 2002 following the acquisition of an Israeli company that was developing a line of blood flow measurement devices.

Although we had expanded our strategic focus with the addition of medical devices outside the oncology field, we continued to look for other avenues to reinvigorate our radiopharmaceutical development portfolio. During 2004, our efforts resulted in a number of positive events that caused us to take steps to re-activate our radiopharmaceutical and therapeutic initiatives. As a result of our efforts over the past few years, we now have one radiopharmaceutical product, Lymphoseek®, in the final stages of completion of one pivotal Phase 3 clinical trial and on the verge of commencing another pivotal Phase 3 clinical trial. Our activity related to our second radiopharmaceutical product, RIGScan® CR, increased significantly during 2008 as we sought and received formal scientific advice on our regulatory and clinical pathways from the European Medicinal Evaluation Agency (EMA) and are taking steps to obtain similar feedback from the U.S. Food and Drug Administration (FDA). Our subsidiary, Cira Biosciences, Inc. (Cira Bio), also took steps in early 2008 to identify funding sources to assist it in evaluating the market opportunities for yet another technology platform, activated cellular therapy (ACT); however, such steps have been unsuccessful to date.

We believe that our virtual business model is unique within our industry as we combine revenue generation from medical devices covering our public company overhead while we devote capital raised through financing efforts to the development of products such as Lymphoseek which possess even greater potential for shareholder return. In addition, we have sought to maintain a development pipeline with additional longer-term return potential such as RIGScan CR and ACT that provide the opportunity for incremental return on the achievement of key development and funding milestones.

## Our Technology

### Gamma Detection Devices

Through 2008, our line of gamma radiation detection devices has generated substantially all of our revenue. Our gamma detection systems are 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 FDA and other international regulatory agencies for marketing and commercial distribution throughout most major global markets.

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 pen flashlight. The neoprobe® GDS gamma detection system, originally released in 1998 under the name neo2000®, is the fourth generation of our gamma detection products. The neoprobe GDS is designed as a platform for future growth of our instrument business. The neoprobe GDS 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 four major software upgrades for customer units designed to improve the utility of the system and/or offer the users additional features, including our most recent release that enables our entire installed base of neoprobe GDS users to use our wireless gamma detection probes based on Bluetooth® wireless technology that have been commercially launched over the last few years. Generally, these software upgrades have been included in new units offered for sale but have also been offered for sale separately.

Surgeons are using our gamma detection devices in a surgical application referred to as sentinel lymph node biopsy (SLNB) or intraoperative lymphatic mapping (ILM or lymphatic mapping). SLNB helps trace the lymphatic drainage 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. SLNB 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 have 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.

The application of SLNB to solid tumor cancer treatment has been most widely developed in the breast cancer and melanoma indications. Numerous clinical studies, involving a total of nearly 2,000 patients and published in peer-reviewed medical journals as far back as *Oncology* (January 1999) and *The Journal of The American College of Surgeons* (December 2000), have indicated SLNB is approximately 97% accurate in predicting the presence or absence of disease spread in melanoma and breast cancers. Consequently, it is estimated that more than 80% of breast cancer patients who would otherwise have undergone full axillary lymph node dissections (ALND), involving the removal of as many as 20 - 30 lymph nodes, might be spared this radical surgical procedure if the sentinel node was found to be free of cancer. Surgeons practicing SLNB 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 topic of SLNB. Furthermore, a number of thought leaders and cancer treatment institutions have recognized and embraced the technology as standard of care for melanoma and for breast cancer. Our marketing partner continues to see strong sales, especially for use in breast cancer treatment. SLNB in breast cancer has been the subject of national and international clinical trials, including one major study sponsored by the U.S. Department of Defense and the National Cancer Institute (NCI) and one sponsored by the American College of Surgeons. The first of these trials completed accrual approximately three years ago. While we are not aware of the exact timing of publication or presentation of results from these trials, it is possible that such data may be available later this year. Accrual on the second trial was halted early (in 2007), due, we believe, to the overwhelming desire of patients to be treated with SLNB rather than be randomized in a trial whereby they might receive a full axillary dissection. We believe that once data from these trials are widely published, there may be an additional demand for our devices from those surgeons who have not yet adopted the SLNB procedure. 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 detection devices are used, that while we are potentially reaching saturation at the major cancer centers and teaching institutions, a significant portion of the global market for gamma detection devices such as ours remains untapped. We also believe we are beginning to see the development of a replacement device market in the gamma detection device sector, aided in part by new offerings such as our wireless probes, as devices purchased over ten years ago during the early years of lymphatic mapping begin to be retired. However, the impact of current economic conditions on our business is uncertain at this time.

Although lymphatic mapping has found its greatest acceptance thus far in breast cancer and melanoma, we believe that Lymphoseek may be instrumental in extending SLNB into other solid tumor cancers in which surgeons are currently investigating such as prostate, gastric, colon, head and neck, and non-small cell lung cancers. Investigations in these other cancer types have thus far met with mixed levels of success; however, we believe our development of Lymphoseek may positively impact the effectiveness of SLNB in such indications. Surgeons have also been using our devices for other gamma-guided surgery applications, such as evaluating the thyroid function and conducting parathyroid surgery, and in determining the state of disease in patients with vulvar and penile cancers. Expanding the application of SLNB beyond the current primary uses in the treatment of breast cancer and melanoma is a primary focus of our strategy regarding our gamma-guided surgery products and is consistent with our Phase 3 Lymphoseek clinical trial strategy. To support that expansion, we continue to work with our marketing and distribution partners to develop additional software-based enhancements to the neoprobe GDS platform as well as the wireless probes that were introduced over the last few years and the new high energy probe we launched at the recent Society of Surgical Oncology (SSO) 62nd Annual Cancer Symposium.

#### Blood Flow Measurement Devices

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

- real-time monitoring;
- intra-operative quantification;

- non-invasive diagnostics; and
- evaluation of cardiac function.

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.

Our wholly-owned subsidiary, Cardiosonix Ltd. (Cardiosonix) has developed and is commercializing the Quantix product line that employs a unique and proprietary technology for measurement of blood flow volume, velocity and several other hemodynamic parameters, permitting 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 device uses 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. Through 2008, we have focused our blood flow measurement efforts primarily on measuring blood flow in cardiac bypass grafts and have performed some preliminary investigations of application of the technology for use in vascular assessment, particularly associated with dialysis applications. Thus far, our efforts have met with limited success.

Quantix/ORTM is designed to permit cardiovascular surgeons 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 typically resorts to using his or her 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, simple and low cost; 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 pulse 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 measurable 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 non-skeletonized vessel measurements are required. As a result, a majority of surgeons generally resort to finger palpation to qualitatively, rather than quantitatively, measure vessel perfusion.

During 2009, we intend to continue the modest support activities we have underway to support greater penetration of the Quantix/OR in cardiovascular and vascular applications. However, given our limited success in achieving market penetration to-date and the minimal support activities we are currently devoting to the product line, we cannot assure



you that any of Cardiosonix's products will achieve market acceptance. As a result, we may be forced to consider other strategic alternatives. See 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 are used. The product we are developing with the greatest near-term potential in this area is Lymphoseek, a proprietary drug compound under exclusive worldwide license from the University of California, San Diego (UCSD). The UCSD license grants Neoprobe the commercialization rights to Lymphoseek for diagnostic imaging and intraoperative detection applications. If proven effective and cleared for commercial sale, Lymphoseek would be the first radiopharmaceutical product specifically designed and labeled for the targeting of sentinel lymph nodes.

Neoprobe and UCSD completed the initial pre-clinical evaluations of Lymphoseek in 2001. Since that time, UCSD has completed or initiated five Phase 1 clinical trials involving Lymphoseek. The status of these trials is listed below:

Indication	Phase	Number of Patients	Status
Breast (peritumoral injection)	1	24	Completed
Melanoma	1	24	Completed
Breast (intra-dermal injection, next day surgery)	1	60	Ongoing
Prostate	1	20	Ongoing
Colon	1	20	Ongoing
Breast and Melanoma	2	80	Completed
Breast and Melanoma	3	150*	Completing
Head and Neck Squamous Cell Carcinoma ("Sentinel")	3	180	Pending

\* Patient number is approximate and is based on an estimated average number of lymph nodes expected to be removed from each patient. The trial size is based on extracting a total of 203 lymph nodes from the patients enrolled.

The Phase 1 studies were or are being 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 some of these clinical evaluations of Lymphoseek have been presented at recent meetings of the Society of Nuclear Medicine, the SSO and the World Sentinel Node Congress. The ongoing breast, prostate and colon studies are being conducted under Neoprobe's investigational new drug (IND) application that has been cleared with FDA using drug product supplied by Neoprobe.

In November 2003, we met with the Interagency Council on Biomedical Imaging in Oncology, 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 an IND application to FDA to support the marketing clearance of Lymphoseek.

In early 2005, we announced that FDA had accepted our application to establish a corporate IND for Lymphoseek. With the transfer of the UCSD physician IND to Neoprobe, we assumed full clinical and commercial responsibility for the development of Lymphoseek. Following the establishment of the corporate IND, Neoprobe's clinical and regulatory personnel began discussions with FDA regarding the clinical development program for Lymphoseek.



As a “first in class” drug, Neoprobe was advised that additional non-clinical studies needed to be completed before additional clinical testing of the drug could occur in humans. The non-clinical testing was successfully completed in late 2005 and the reports were filed with FDA in December 2005. The seven studies included repeat administrations of Lymphoseek at dosages significantly in excess of the anticipated clinical dosage. None of the non-clinical studies revealed any toxicity issues associated with the drug.

Upon the submission of the IND and draft Phase 2 protocol, FDA advised Neoprobe that commercially produced Lymphoseek would need to be used in the Phase 2 clinical study, as opposed to using drug previously manufactured in laboratories at UCSD. Also, the regulatory agencies raised a number of Chemistry, Manufacturing and Control (CMC) questions regarding the drug compound and its complete characterization. Neoprobe began the transfer of bulk drug manufacturing to Reliable Biopharmaceutical Corporation (Reliable) early in 2005 and engaged OSO BioPharmaceuticals Manufacturing LLC (OSO Bio, formerly Cardinal Health PTS) to develop and validate procedures and assays to establish commercial standards for the formulation, filling and lyophilization of the drug compound. We submitted an initial CMC response to FDA in 2006.

We received clearance from FDA in May 2006 to move forward with patient enrollment for a multi-center Phase 2 clinical study of Lymphoseek. The first of our Phase 2 clinical sites received clearance from its internal clinical review committee, or Institutional Review Board (IRB), in July 2006. The IRB clearance permitted us to finalize arrangements to begin patient screening and enrollment activities for the Phase 2 trial, and we began patient enrollment in September 2006 and completed enrollment of the 80 patients in June 2007. We announced positive preliminary efficacy results from our Phase 2 Lymphoseek trial in June 2007 and final results in December 2007. Localization of Lymphoseek to lymphoid tissue was confirmed by pathology in over 99% of the lymph node tissue samples removed during the Phase 2 trial. We held an end of Phase 2 meeting with FDA during late October 2007 during which the final results were reviewed. The Phase 2 study was conducted at five of the leading cancer centers in the U.S.: John Wayne Cancer Center; University of California, San Francisco; MD Anderson Cancer Center; University Hospital Cleveland (Case Western Reserve); and the University of Louisville.

Based on discussions and correspondence with FDA, we proposed to FDA that we conduct two separate Phase 3 studies to support an application for marketing clearance. During 2008, we initiated patient enrollment in the first of the two phase 3 clinical studies to be conducted in patients with either breast cancer or melanoma. In March 2009, we announced that this first study had reached the accrual of 203 lymph nodes, the study’s primary accrual objective. In the previous Phase 2 multi-center study of Lymphoseek, which was also conducted in patients with breast cancer or melanoma, an overall localization rate of 94% in lymph nodes was achieved in those patients where both a vital blue dye and Lymphoseek were used. A similar concordance rate of 94% was established by Neoprobe and FDA as the primary efficacy objective for the Phase 3 trial, NEO3-05. Based upon the intraoperative worksheets and preliminary pathology reports, we believe that the primary efficacy end-point of NEO3-05 has been achieved and no incidents related to drug safety have been reported in the Lymphoseek studies. Upon completion of a full analysis of the Phase 3 data, we will provide a complete update on the study results after all clinical data has been reviewed by our internal clinical team and external consultants. We expect full data will be available in the 2nd quarter of 2009.

We have provided FDA and EMEA with the full protocol and associated materials for a second Phase 3 study to be conducted in patients with head and neck squamous cell carcinoma. This second Phase 3 study is designed to validate Lymphoseek as a sentinel lymph node targeting agent. Our discussions with FDA and EMEA have also suggested that the Phase 3 trials will support an intended labeling for use of Lymphoseek in sentinel lymph node biopsy procedures. We believe such an indication would be beneficial to the marketing and commercial adoption of Lymphoseek in the U.S. and European Union (EU). We plan to have approximately 25 – 35 institutions, located primarily in the U.S. and EU, participate in the trial. The trial protocol is currently under review at a number of these institutions. We expect to receive our first IRB clearance at a participating institution shortly and expect patient accrual to commence during the second quarter of 2009.



Our goal remains to file the new drug application for Lymphoseek in early 2010; however, this will be dependent upon our ability to commence and successfully conclude the Phase 3 clinical studies in a timely fashion. We expect to incur approximately \$4 million in out-of-pocket development costs in 2009 related to the clinical and regulatory development of Lymphoseek. Depending on the timing and outcome of the FDA regulatory review cycle, we believe that Lymphoseek can be commercialized by early 2011. We cannot assure you, however, that this product will achieve regulatory approval, or if approved, that it will achieve market acceptance. See 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. 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 targeting agent consisting of a radiolabeled murine monoclonal antibody (CC49 MAb). The radiolabel used is <sup>125</sup>I, a 27 - 35 KeV emitting isotope. The CC49 MAb was developed by the NCI and is 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 antigen 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 3 studies, NEO2-13 and NEO2-14, of RIGScan CR in the mid-1990s in patients with primary and metastatic colorectal cancer, respectively. Both studies were multi-institutional involving cancer treatment institutions in the U.S., Israel, and the EU. The primary endpoint of both studies was to demonstrate that RIGScan CR detected pathology-confirmed disease that had not been detected 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 EMEA and FDA for marketing approval of RIGScan CR for the detection of metastatic colorectal cancer.



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.

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 EMEA. Both FDA and EMEA acknowledged that our studies met the diagnostic endpoint of the Phase 3 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 withdrew its application to 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. The data includes publication by some of the primary investigators involved in the Phase 3 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 learned that FDA has held open the BLA originally filed with FDA in 1996. Based primarily on this information, we requested a meeting with FDA in 2004 to discuss the possible next steps for evaluating the survival related to our previous Phase 3 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.

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 also indicated that it would consider possible prognostic indications for RIGScan CR and that survival data from one of our earlier Phase 3 studies could be supportive of a prognostic indication.

It should be noted, however, that the RIGScan CR biologic drug has not been produced for several years and based on the feedback we recently received from EMEA, we would have to perform some additional work related to ensuring the drug cell line is still viable and submit this data to EMEA and possibly FDA for their evaluation in connection with preparations to restart pivotal clinical trials. 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 re-establish radiolabeling capabilities for the CC49 antibody in order to meet the regulatory needs for the RIGScan CR product.

In parallel with our ongoing 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.

In November 2005, Neoprobe submitted a corporate IND application for the modified humanized version of RIGScan CR. With the establishment of the corporate IND, responsibility for the clinical and commercial development of the humanized version of RIGScan CR was officially transferred from a physician sponsored IND to Neoprobe. Prior to the evaluation of the modified antibody in a Phase 1 clinical trial, all clinical development of RIGScan CR had been conducted with a murine (i.e., mouse DNA-based) version of a monoclonal antibody. The Phase 1 trial was the first test in human patients using a modified version of the antibody from which the prominent parts of the mouse DNA chain had been removed. In early 2006, we filed an IND amendment that included a final report to FDA of the Phase 1 study.

Over the past few years, the progress we have made in advancing our RIGScan CR development program while incurring little in the way of research expenses. Our RIGS technology, which had been essentially inactive since failing to gain approval following our original license application in 1997, has been the subject of renewed interest due primarily to the analysis of survival data related to patients who participated in the original Phase 3 clinical studies that were completed in 1996. After a successful pre-submission meeting with EMEA in July 2008, we submitted a plan during the third quarter on how we would propose to complete clinical development plan for RIGScan CR. The clinical protocol we submitted to EMEA involves approximately 400 patients in a randomized trial of patients with colorectal cancer. The participants in the trial would be randomized to either a control or RIGS treatment arm. Patients randomized to the RIGS arm would have their disease status evaluated at the end of their cancer surgery to determine the presence or absence of RIGS-positive tissue. Patients in both randomized arms would be followed to determine if patients with RIGS-positive status have a lower overall survival rate and/or a higher occurrence of disease recurrence. The hypothesis for the trial is based upon the data from the earlier NEO2-13 and NEO2-14 trial results.

We continue to believe it will be necessary for us to identify a development partner or an alternative funding source in order to prepare for and fund the pivotal clinical testing that will be necessary to gain marketing clearance for RIGScan CR. In the past, we have engaged in discussions with various parties regarding such a partnership. We believe the recently clarified regulatory pathway approved by EMEA will assist us in those efforts. However, 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. We cannot assure you that we will be able to complete definitive agreements with a development partner or obtain financing to fund development of the RIGS technology and do not know if such arrangements could be obtained on a timely basis on terms acceptable to us, or at all. We also cannot assure you that FDA or EMEA will clear our RIGS products for marketing or that any such products will be successfully introduced or achieve market acceptance.

## Activated Cellular Therapy

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.

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 patients afflicted with viral and autoimmune disease as well as oncology patients. We have seen promising efficacy of this technology demonstrated from six Phase 1 clinical trials covering the oncology, viral and autoimmune applications.

In 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, 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 exclusive 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 exclusive licenses to several pending patent applications.

In 2006, Cira Bio 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. In August 2007 we entered into a Stock and Technology Option Agreement whereby Neoprobe gained the option to purchase the remaining 10% of Cira Bio from Cira LLC for \$250,000 in connection with the successful completion of a financing transaction by Cira Bio. In the first quarter of 2008, we also entered into discussions with an investment banking firm to help us gauge the interest of potential investment in the ACT technology. We still hope to raise funds through Cira Bio to support the continued development of ACT; however, our fundraising efforts have thus far not been successful and our option to purchase the remaining 10% interest in Cira Bio expired on June 30, 2008. If we are successful in identifying a funding source, we expect that any funding would likely be accomplished by an investment directly into Cira Bio, so that the funds raised would not dilute current Neoprobe shareholders. Obtaining this funding would 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 stockholders and the patients who could benefit from these treatments. However, we do not know if we will be successful in obtaining funding on terms acceptable to us, or at all. In the event we fail to obtain financing for Cira Bio, the technology rights for the oncology applications of ACT may revert back to Neoprobe and the technology rights for the viral and autoimmune applications may revert back to Cira LLC upon notice by either party. See Risk Factors.

## Market Overviews

The medical device marketplace is a fast growing market. Medical Device & Diagnostic Industry magazine has reported an annual medical device and diagnostic market of as much as \$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 has been estimated to be responsible for over 565,000 deaths annually in 2008 in the U.S. alone. The NIH has estimated the overall annual costs for cancer (the primary focus of our gamma detection and pharmaceutical products) for the U.S. for 2007 at \$219.2 billion: \$89.0 billion for direct medical costs, \$18.2 billion for indirect morbidity, and \$112.0 billion for indirect mortality. Our line of gamma detection systems is currently used primarily in the application of SLNB in breast cancer and melanoma which, according to the ACS, have been estimated to account for 13% and 4%, respectively, of new cancer cases which occurred in the U.S. in 2008.

The NIH has estimated that breast cancer will annually affect half a million 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. The incidence of breast cancer, while starting to show minor declines in the past year or so, generally 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. While the incidence rate for breast cancer appears to be decreasing, the overall number of new cases of breast cancer is still increasing. According to the ACS, over 182,000 new cases of invasive breast cancer are expected to be diagnosed and approximately 41,000 women are estimated to have died from the disease during 2008 in the U.S. alone. Thus, we believe that the significant aging of the population, combined with improved education and awareness of breast cancer and diagnostic methods, will continue to lead to an increased number of breast cancer surgical diagnostic procedures.

Approximately 80% of the patients diagnosed with breast cancer undergo a lymph node dissection (either ALND or SLNB) to determine if the disease has spread. While many breast cancer patients are treated in large cancer centers or university hospitals, regional and/or community hospitals continue to treat the majority of breast cancer patients. Over 10,000 hospitals are located in the markets targeted for our gamma detection SLNB products. We believe a significant portion of the potential market for gamma detection devices remains unpenetrated and that a replacement market is beginning to develop as units placed in the early years of SLNB begin to exceed over ten years of use. In addition, 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 SLNB to additional indications, such as gastric, non-small cell lung and other solid tumor cancers.

We estimate the total market potential for Lymphoseek, if ultimately approved for all of these indications, could exceed \$250 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 has also estimated that nearly 148,000 new incidences of colon and rectal cancers were expected to occur in the U.S. in 2008. 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 be in excess of \$2 billion annually, depending on the level of reimbursement allowed. 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. The National Center for Healthcare Services (NCHS) registered nearly 7 million inpatient cardiovascular procedures in the U.S. during 2005 with a primary diagnosis of cardiovascular

disease. In the U.S. in 2005, the NCHS estimates that there were 469,000 coronary artery bypass surgeries performed on 261,000 patients. We, as well as our competitors and other industry analysts, generally estimate the rest of the world's incidence of such modalities at approximately equal to as much as two times U.S. estimates.

The American Heart Association (AHA) last year estimated the total cost of cardiovascular diseases and stroke in the United States would exceed \$448 billion in 2008. A substantial portion of these expenditures is expected to be for non-invasive image and intravascular examination.

Based on data obtained from the AHA, the Society of Thoracic Surgeons and the American Hospital Association, it is estimated that there are approximately 500,000 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 equal to as much as two times the U.S. totals.

At present, we would estimate that less than 25% of by-pass procedures involve blood flow measurement. Industry analysts have estimated the potential market for blood flow measurement devices will exceed \$240 million annually by 2010. However, at the present state of market development and acceptance of blood flow measurement within the medical community, the penetrable market is likely significantly less. Our success to date has been limited and we cannot assure you that Cardiosonix's products will achieve greater market acceptance and generate the level of sales or prices anticipated.

## Marketing and Distribution

### Gamma Detection Devices

We began marketing the neo2000 gamma detection system 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 & Johnson company. In Japan, however, we market our products through a pre-existing relationship with Century Medical, Inc.

The heart of our gamma detection product line, the neoprobe GDS, is a control unit that is software-upgradeable, permitting product enhancements without costly remanufacturing. Since the original launch of the GDS' predecessor platform, the neo2000 (in 1998), we have also introduced a number of enhanced radiation detection probes optimized for lymphatic mapping procedures, including three wireless probes, as well as a new probe optimized for the detection of high energy radioisotopes. We have also developed four major software upgrades for the system that have been made available for sale to customers. We intend to continue developing additional SLNB-related probes and instrument products in cooperation with EES to maintain our leadership position in the gamma detection field.

Physician training is critical to the use and adoption of SLNB products by surgeons and other medical professionals. Our company and our marketing partners have established relationships with leaders in the SLNB 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 SLNB training courses available to surgeons.

We entered into a 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 its first two-year extension option, and in March 2006 EES exercised its option for the second and final two-year term extension, thus extending the term of our the agreement through the end of 2008. In December 2007, Neoprobe and EES executed an amendment to the distribution agreement which extended the agreement through the end of 2013. Under this agreement, we manufacture and sell our SLNB products almost exclusively to EES, who distributes the products globally (except for Japan). EES has no ongoing purchase or reimbursement commitments to us other than the rolling four-month binding purchase commitment for gamma detection devices and certain annual minimum sales levels in order to maintain their exclusivity in distribution in most global markets. In addition, the economic terms of the revenue sharing from the end customer sale of our gamma detection devices increased commencing in January 2009. 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 Risk Factors.

### Gamma Detection Radiopharmaceuticals

During the fourth quarter of 2007, we executed an agreement with Cardinal Health, Inc.'s radiopharmaceutical distribution division (Cardinal Health) for the exclusive distribution of Lymphoseek in the United States. The agreement is for a term of five years from the date of marketing clearance of a NDA from FDA. Under the terms of our agreement with Cardinal Health, Neoprobe will receive a share of each patient dose sold. In addition, Neoprobe will receive up to \$3 million in payments upon the achievement of certain sales milestones by Cardinal Health. We do not currently have collaborative agreements covering Lymphoseek in other areas of the world or for RIGScan CR or ACT. We cannot assure you that we will be successful in securing collaborative partners for other global markets or radiopharmaceutical products, or that we will be able to negotiate acceptable terms for such arrangements. We believe the most preferable and likely distribution partners for Lymphoseek would be entities with established radiopharmaceutical distribution channels, although it is possible that other entities with more traditional oncology pharmaceutical portfolios may also have interest.

With respect to RIGScan CR, we believe there are development milestones that can be achieved prior to the need for significant capital investment in RIGScan CR, such as harmonizing the regulatory requirements in the US and EU for the planned Phase 3 trial. We continue to believe it will be necessary for us to identify a development partner or an alternative funding source in order to prepare for and to fund the pivotal clinical testing that will be necessary to gain marketing clearance for RIGScan CR. At the present time, while we have parties who have indicated an interest in entering into a development relationship, we do not believe these efforts will result in a definitive partnership at least until a regulatory and development pathway is obtained. We anticipate continuing discussions for RIGScan CR as we move forward with the clinical development of the product; however, we cannot assure you that we will be able to secure marketing and distribution partners for the product, or if secured, that such arrangements will result in significant sales of RIGScan CR.

### Blood Flow Measurement Devices

Our initial blood flow measurement device, the Quantix/OR has received marketing clearance in the U.S. and the EU and certain other foreign markets. Our goal is to ensure sales and distribution coverage through third parties of substantially all of the U.S., the EU, the Pacific Rim of Asia and selective markets in the rest of the world. Our marketing partnership efforts in the U.S. and EU to date have been largely ineffective in penetrating our target market and as a result we are re-evaluating our marketing representation in those markets and investigating other distribution alternatives. In addition, we have distribution arrangements in place covering major portions of Central and South America.

Our time and effort in the marketing and sales of blood flow devices through 2008 has been to improve market penetration for the Quantix/OR through working with third party distributors. We continue to critically evaluate our outlook for our blood flow measurement business and investigate other strategic alternatives.

### Manufacturing

#### Medical 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 Risk Factors. We have devoted significant resources to develop production capability of our gamma detection systems at qualified contract manufacturers. Production of the neoprobe GDS control unit, the 14mm probe, the 11mm laparoscopic probe, and the wireless probes involve the manufacture of components by a combination of subcontractors, including but not limited to, eV Products, a division of II-VI Incorporated (eV), and TriVirix International, Inc. (TriVirix). We also purchase

certain accessories for our line of gamma detection systems from other qualified manufacturers.

We have purchased certain solid-state crystals and associated electronics used in the manufacture of our proprietary line of hand-held gamma detection probes from eV. We do not currently have a supply agreement with eV, however we currently purchase from them under extended blanket purchase orders. The number of potential suppliers of such solid-state crystals is limited. In the event we are unable to secure a viable alternative source of supply should we become unable to obtain crystals from eV, 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 and/or final assembly of our gamma detection products, including probes and control units, and our blood flow measurement control units. The original term of this agreement expired in February 2007 but has been extended under the automatic renewal terms of the agreement through February 2010. The Agreement will continue to be automatically extended for successive one-year periods unless six months notice is provided by either party.

The Quantix blood flow measurement devices distributed through early 2006 were manufactured by Cardiosonix in Israel. In early 2006, we received approval from the Office of the Chief Scientist (OCS) of Israel to transfer manufacturing rights for the Quantix devices to Neoprobe. See Risk Factors. Future assembly of Quantix blood flow control units will therefore be done under the terms of the Product Supply Agreement we have in place with TriVirix for the assembly of our gamma detection products. Assembly of the Quantix/OR control units started at TriVirix in March 2006. We currently purchase ultrasound transducer modules and probe subassemblies from Vermon S.A. of France under purchase orders. The ultrasound probe assemblies are then completed by Technical Services for Electronics, Inc., also under purchase orders.

We cannot assure you that we will be able to maintain agreements or other purchasing arrangements 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 Risk Factors.

#### Gamma Detection Radiopharmaceuticals

In preparation for the commencement of a multi-center clinical evaluation of Lymphoseek, Neoprobe engaged drug manufacturing organizations to produce the drug that was used in the Phase 2 trial and is expected to be used in the pivotal (i.e., Phase 3) clinical trials. Reliable has produced the active chemical compound and OSO Bio has performed final product manufacturing including final drug formulation, lyophilization (i.e., freeze-drying) and packaging processes. Once packaged, the vialled drug can then be shipped to a hospital or regional commercial radiopharmacy where it can be made radioactive (i.e., radiolabeled) with Tc99m to become Lymphoseek. The commercial manufacturing processes at Reliable and OSO Bio are being validated and both organizations have assisted Neoprobe in the preparation of the chemistry, manufacturing and control sections of our submissions to FDA and EMEA. Both Reliable and OSO Bio are registered manufacturers with FDA and/or EMEA. At this point, drug product produced by Reliable and OSO Bio has been produced under clinical development agreements. Commercial supply and distribution agreements are being negotiated with both Reliable and OSO Bio. We cannot assure you that we will be successful in reaching such agreements with Reliable or OSO Bio 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 also 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 CR product; however, we have not yet finalized agreements with these entities. We anticipate finalizing these discussions following securing a development partner in order to support the commencement of future 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 Risk Factors.

## 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 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 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 continued emergence of SLNB, 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 and/or marketed by Care Wise Medical Products Corporation, Intra-Medical Imaging LLC, RMD Instruments LLC (a subsidiary of Dynasil Corporation), SenoRx, Eurorad S.A and other companies.

It is often difficult to glean accurate competitive information within the lymphatic mapping field, primarily because most of our competitors are either subsidiaries or divisions of larger corporations or privately held corporations, whose sales revenue or volume data is 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 using lymphatic mapping 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 of the SLNB 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 Risk Factors.



### 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 for which Lymphoseek is intended currently use other radiopharmaceuticals such as a sulphur-colloid compound in the U.S. and other colloidal compounds in other markets. However, these drugs are being used “off-label” in most major global markets (i.e., they are not specifically indicated for use as a sentinel node targeting agent). As such, we believe that Lymphoseek, if ultimately approved, would be the first drug specifically labeled for use as a sentinel lymph node 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. We believe our device is most directly competitive in the cardiac bypass graft (CABG) marketplace with Transit Time Ultrasound (TT) Flowmetry. TT is the leading modality for blood flow measurement 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. In addition, there are other competitive technologies in CABG applications that utilize Doppler ultrasound. 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 also technician-dependent, often cumbersome and does not offer monitoring capabilities. Plain Doppler systems provide only blood flow velocity rather than volume flow.

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 blood flow measurement in the broader vascular assessment market, the following companies compete most directly with the Quantix products in the CABG market: Transonic Systems, Inc., Medi-Stim AS, and Carolina Medical, Inc.

### 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. Approximately 20 instrument patents issued in the United States as well as major foreign markets protect our gamma detection technology.



Cardiosonix has also applied for patent coverage for the key elements of its Doppler blood flow technology in 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.

Lymphoseek is also the subject of patents and patent applications in the United States and certain major foreign markets. The patents and patent applications are held by The Regents of the University of California and have been licensed exclusively to Neoprobe for lymphatic tissue imaging and intraoperative detection worldwide. The first composition of matter patent covering Lymphoseek was issued in the United States in June 2002. The claims of the composition of matter patent covering Lymphoseek have been allowed in the EU and issued in the majority of EU countries in 2005. The composition of matter patent is being prosecuted in Japan and we have received notice of the allowance of the underlying claims.

We continue to support 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. 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 was issued in 2004 and additional patent applications are pending. We have a license to these patents through the NIH; however, our license is subject to ongoing diligence requirements.

The activated cellular therapy technology of Cira Bio is the subject of issued patents in the United States to which Neoprobe has exclusive 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 issued 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 and Trademark Office. Cira Bio has received favorable office action correspondence on both applications.

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, 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.

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

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

## 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

As a manufacturer of medical devices sold in various global markets, we are required by regulatory agency regulations to manufacture the devices under recognized quality standards and controls. Our medical devices are regulated in the United States by FDA in accordance with 21CFR requirements, in the EU according to the Medical Device Directive (93/42/EEC), and in Canada and Japan according to the Medical Devices Regulation. These regulatory requirements for quality systems are prescribed in the international standard ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. To ensure continued compliance in our daily processes, we have

established and maintain the Neoprobe Corporate Quality Management System, which is based on the ISO 13485 standard. These requirements can also be extended to drug and biologic products regarding our future product portfolio.

Our first generation gamma detection instrument received 510(k) marketing clearance from FDA in December 1986 with modified versions receiving similar clearances in 1992 through 1997. In March 1998, FDA reclassified "nuclear uptake detectors" as Class 1 and conditionally exempt from 510(k) with full quality controls. We obtained the European CE mark, by "self-declaration," for the neo2000 device in January 1999, with full quality controls. The gamma detection products are Class IIa in the EU. We maintain a "manufacturer's license" in order to import our gamma detection products into Canada, with full quality controls. The gamma detection products are Class II in Canada.

Similar to the gamma detection products, and under our Quality Management System controls, the Cardiosonix products have received 510(k) and CE mark clearance to market the Quantix/OR device in the U.S. and EU, respectively. Our distribution partners in certain foreign markets other than the EU are seeking marketing clearances, as required, for the Quantix/OR. The Quantix/OR product is Class II in the U.S. and Class IIa in the EU.

#### 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 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.

#### Research and Development

We spent approximately \$4.5 million and \$2.9 million on research and development activities in the fiscal years ended December 31, 2008, and December 31, 2007, respectively.

Employees

As of March 16, 2009, we had 25 full-time employees. We consider our relations with our employees to generally be good.

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## Item 1A. 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 report, 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 \$148.8 million and had an overall deficit in stockholders' equity as of December 31, 2008. Although we were profitable in 2000 and in 2001, we incurred substantial losses in the years prior to that, and again in 2002 and subsequent years. 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 expenses in the foreseeable future, primarily related to the completion of development and commercialization of Lymphoseek, but also potentially related to RIGS and our device product lines. 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 handheld gamma detection devices is currently limited to one surgical procedure, SLNB, used in the diagnosis and treatment of two primary types of cancer: melanoma and breast cancer. While the adoption of SLNB within the breast and melanoma indications appears to be widespread, expansion of SLNB to other indications such as head and neck, colorectal and prostate cancers is likely dependent on a better lymphatic tissue targeting agent than is currently available. Without expanded indications in which to apply SLNB, it is likely that gamma detection devices will eventually reach market saturation. 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.

To date, our efforts to place Cardiosonix's Quantix products have met with limited success. The long-term commercial success of the Quantix product line will require much more widespread acceptance of our blood flow measurement products than we have experienced to date. Widespread acceptance of blood flow measurement would represent a significant change in current 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 Quantix product line will never achieve the broad market acceptance necessary to become a commercial success.

Our radiopharmaceutical product candidates, Lymphoseek and RIGScan CR, 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.

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 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.



We believe that we have access to sufficient financial resources with which to fund our operations or those of our subsidiaries for the foreseeable future. We expect to raise additional capital during 2009 through existing financing facilities already available to us in order to continue executing on our current business plan. The continuation of the current worldwide financial crisis and depressed stock market valuations may adversely affect our ability to raise additional capital, either under facilities in place or from new sources of capital. If we are unsuccessful in raising additional capital, closing on financing under already agreed to terms, or the terms of raising such capital are unacceptable, we may have to modify our business plan and/or significantly curtail our planned development activities and other operations.

In December 2006, we entered into a common stock purchase agreement with Fusion Capital, an Illinois limited liability company, to sell \$6.0 million of our common stock over a 24-month period which ended on November 21, 2008. Through November 21, 2008, we sold Fusion Capital under the agreement 7,568,671 shares for proceeds of \$1.9 million. In December 2008, we entered into an amendment to the agreement which gave us a right to sell an additional \$6.0 million of our common stock to Fusion Capital before March 1, 2011, along with the \$4.1 million of the unsold balance of the \$6.0 million we originally had the right to sell to Fusion Capital under the original agreement. After giving effect to this amendment, the remaining aggregate amount of our common stock we can sell to Fusion Capital is \$10.1 million, and we have reserved a total of 10,654,000 shares of our common stock for sale under the amended agreement. Our right to make sales under the agreement is limited to \$50,000 every two business days, unless our stock price equals or exceeds \$0.30 per share, in which case we can sell greater amounts to Fusion Capital as the price of our common stock increases. Fusion Capital does not have the right or any obligation to purchase any shares on any business day that the market price of our common stock is less than \$0.20 per share. Assuming all 10,654,000 shares are sold, the selling price per share would have to average approximately \$0.94 for us to receive the full \$10.1 million remaining proceeds under the agreement as amended. Assuming we sell to Fusion Capital all 10,654,000 shares at a sale price of \$0.51 per share (the closing sale price of the common stock on March 16, 2009), we would only receive \$5.4 million under the agreement. Under the agreement, we have the right but not the obligation to sell more than the 10,654,000 shares to Fusion Capital. As of the date hereof, we do not currently have any plans or intent to sell to Fusion Capital any shares beyond the 10,654,000 shares. However, if we elect to sell more than the 10,654,000 shares, we must first register any additional shares we may elect to sell to Fusion Capital under the Securities Act before we can sell such additional shares.

The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources, such as through the sale of our products. To the extent that we are unable to make sales to Fusion Capital to meet our capital needs, or to the extent that we decide not to make such sales because of excessive dilution or other reasons, and if we are unable to generate sufficient revenues from sales of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$10.1 million potentially remaining under the agreement with Fusion Capital, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

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. During 2008, we successfully completed a Phase 2 clinical trial for our most advanced radiopharmaceutical product candidate, Lymphoseek. We are in the process of completing first of two pivotal Phase 3 trials for this product in breast cancer or melanoma and have a second trial pending in head and neck squamous cell carcinoma. We have recently obtained approval from EMEA of a Phase 3 clinical protocol for our next radiopharmaceutical candidate, RIGScan CR and are preparing to approach FDA to obtain similar clearance. 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, the participating institutions, FDA or EMEA might delay or halt any clinical trials for our product candidates for various reasons, including:

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

While we have achieved some level of success in our recent Phase 2 and Phase 3 clinical trials for Lymphoseek, the results of these clinical trials, as well as pending and future trials, are subject to review and interpretation by various regulatory bodies during the regulatory review process and may ultimately 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:

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

We recently executed an agreement with Cardinal Health for the distribution of Lymphoseek in the United States. We do not currently have collaborative agreements covering Lymphoseek in other areas of the world or for RIGScan CR or ACT. We cannot assure you that we will be successful in securing collaborative partners for other markets or radiopharmaceutical products, 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, we have had only limited success to date in marketing or selling our Quantix line of blood flow products. 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.

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 in 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 clearance to market 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 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:

- delay marketing of potential products for a considerable period of time;
- limit the indicated uses for which potential products may be marketed;
- impose costly requirements on our activities; and
- 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 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 risks similar 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 clearance 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 clearance, 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.

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:

- restrictions on the products, manufacturers or manufacturing processes;
  - warning letters;
  - civil or criminal penalties;
  - fines;
  - injunctions;
  - product seizures or detentions;
  - import bans;
- voluntary or mandatory product recalls and publicity requirements;
  - suspension or withdrawal of regulatory approvals;
  - total or partial suspension of production; and
- 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 measurement 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 initial blood flow product, the Quantix/OR. We may not be able to obtain clearance to market 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 neoprobe GDS 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 quality system 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 detection 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 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.

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 radiopharmaceutical 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, to control the escalation of healthcare expenditures within the economy and to 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.

The resale of our common stock sold to investors in private placements may cause dilution and cause the price of our common stock to decline.

Over the past few years, we completed various financings in which we issued common stock, convertible notes, warrants and other securities convertible into common stock to certain private investors. The terms of these transactions require that we file registration statements with the Securities and Exchange Commission under which the investors may resell to the public common stock acquired in these transactions, as well as common stock acquired on the exercise of the warrants and convertible securities held by them. Further, some or all of the common stock sold in these transactions may become eligible for resale without registration under the provisions of Rule 144, upon satisfaction of the holding period and other requirements of the Rule.



As described earlier in this Item 1A, as required by our financing arrangements with Fusion Capital, we have filed a registration statement registering for resale a total of 11,500,000 common shares, consisting of (i) 10,654,000 shares which we may sell to Fusion Capital pursuant to the amended common stock purchase agreement, (ii) 360,000 shares issued to Fusion Capital in consideration for its agreement to the amendment; and (iii) 486,000 commitment fee shares to be issued pro rata as we sell the first \$4.1 million of common stock under the amended agreement. The number of shares ultimately sold under the registration statement will be dependent upon the number of shares purchased by Fusion Capital under the amended agreement. It is anticipated that these shares will be sold from time to time over a period ending on March 1, 2011, at prices that will fluctuate based on changes in the market price of our common stock over that period. We have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

On December 26, 2007, we entered into a Securities Purchase Agreement (SPA) with Platinum-Montaur Life Sciences, LLC (Montaur), pursuant to which we issued Montaur a 10% Series A Convertible Senior Secured Promissory Note in the principal amount of \$7,000,000, due December 26, 2011 (the Series A Note) and a five-year Series W warrant to purchase 6,000,000 shares of our common stock at an exercise price of \$0.32 per share. On April 16, 2008, following receipt by the Company of clearance by FDA to commence a Phase 3 clinical trial for Lymphoseek in patients with breast cancer or melanoma, we amended the SPA and issued Montaur a 10% Series B Convertible Senior Secured Promissory Note in the principal amount of \$3,000,000, also due December 26, 2011 (the Series B Note, and hereinafter referred to collectively with the Series A Note as the Montaur Notes), and a five-year Series X warrant to purchase 8,333,333 shares of our common stock at an exercise price of \$0.46 per share. Montaur may convert the Series B Note into shares of common stock at the conversion price of \$0.36 per share. On December 5, 2008, after the Company had obtained 135 vital blue dye lymph nodes from patients who had completed surgery and the injection of the drug in the Phase 3 clinical trial of Lymphoseek in patients with breast cancer or melanoma, we issued Montaur 3,000 shares of our 8% Series A Cumulative Convertible Preferred Stock (the Preferred Stock) and a five-year Series Y warrant (hereinafter referred to collectively with the Series W warrant and Series X warrant as the Montaur Warrants) to purchase 6,000,000 shares of our common stock, at an exercise price of \$0.575 per share, also for an aggregate purchase price of \$3,000,000.

The Series A Note bears interest at a rate per annum equal to 10%, and is partially convertible at the option of Montaur into common stock at a price of \$0.26 per share. The Series B Note also bears interest at a rate per annum equal to 10%, and is convertible into shares of common stock at the conversion price of \$0.36 per share. Pursuant to the provisions of the Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series A 8% Cumulative Convertible Preferred Stock, Montaur may convert all or any portion of the shares of the Preferred Stock into an aggregate 6,000,000 shares of our common stock, subject to adjustment as described in the Certificate of Designations.

Pursuant to registration rights of Montaur under the SPA, we have filed a registration statement covering the sale by Montaur of up to up to: (i) 6,000,000 shares of common stock issuable upon the conversion of the Preferred Stock; (ii) 6,000,000 shares of common stock issuable upon the exercise of the Series Y warrant; (iii) 3,500,000 shares of common stock issuable as interest and dividends on the Montaur Notes and Preferred Stock; and (iv) 4,666,666 shares of common stock issuable upon the conversion of the Series B Note, for a total of 20,166,666 shares. Additionally, we agreed that within thirty-five days of receipt from Montaur of written request therefor, we would prepare and file an additional "resale" registration statement providing for the resale of: (i) the shares of common stock issuable upon the conversion of the Series A Note; (ii) the shares of common stock issuable upon the exercise of the Series W warrant; (iii) any unregistered shares of common stock issuable upon the conversion of the Series B Note.

The selling stockholders 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 or when the selling stockholders will sell these shares. Depending upon market liquidity at the time, a sale of these shares 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, 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 respond quickly to medical and technological changes through the development and introduction of new products. We may not have the resources to do this. If our products become obsolete and our efforts to develop new products do not result in any commercially successful products, our sales and revenues will decline.

We may not have sufficient legal protection against infringement or loss of our intellectual property, and we may lose rights to our licensed intellectual property if diligence requirements are not met.

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

In the United States, patent applications are secret until patents are issued, 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 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. In January 2006, the OCS consented to the transfer of manufacturing as long as Neoprobe complies with the terms of the OCS statutes under Israeli law. As long as we maintain at least 10% Israeli content in our blood flow devices, we will pay a royalty rate of 4% on sales of applicable blood flow devices and must repay the OCS a total of \$1.2 million in royalties. However, should the amount of Israeli content of our blood flow device products decrease below 10%, the royalty rate could increase to 5% and the total royalty payments due could increase to \$2.3 million. 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 may lose the license rights to certain in-licensed products if we do not exercise adequate diligence.

Our license agreements for Lymphoseek, RIGS, and ACT contain provisions that require that we demonstrate ongoing diligence in the continuing research and development of these potential products. Cira Bio's rights to certain applications of the ACT technology may be affected by its failure to achieve certain capital raising milestones although no such notices to that effect have been received to date. We have provided information, as required or requested, to the licensors of our technology indicating the steps we have taken to demonstrate our diligence and believe we are adequately doing so to meet the terms and/or intent of our license agreements. However, it is possible that the licensors may not consider our actions adequate in demonstrating such diligence. Should we fail to demonstrate the requisite diligence required by any such agreements or as interpreted by the respective licensors, we may lose our development and commercialization rights for the associated product.

We could be damaged by product liability claims.

Our products are used or intended to be used in various clinical or surgical procedures. If one of our products malfunctions or a physician misuses it and injury results to a patient or operator, the injured party could assert a product liability claim against our company. We currently have product liability insurance with a \$10 million per occurrence limit, which we believe is adequate for our current activities. However, we may not be able to continue to

obtain insurance at a reasonable cost. Furthermore, insurance may not be sufficient to cover all of the liabilities resulting from a product liability claim, and we might not have sufficient funds available to pay any claims over the limits of our insurance. Because personal injury claims based on product liability in a medical setting may be very large, an underinsured or an uninsured claim could financially damage our company.

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

Our business has experienced challenges 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 have been pledged as collateral for the \$10 million in principal amount of our Series A and Series B Convertible Notes issued to Montaur, and a \$1 million in principal amount Series B Convertible Note issued to our CEO and members of his family dated July 3, 2007, as amended December 26, 2007 (collectively, 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:

- we pay all principal by December 26, 2011;
- we use the proceeds from the sale of the Notes only for permitted purposes, such as Lymphoseek development and general corporate purposes;
- 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; 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.

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 OTC Bulletin Board (OTCBB). As such, our common stock may have fewer market makers, lower trading volumes and larger spreads between bid and ask prices than securities listed on an exchange such as the New York Stock Exchange or the NASDAQ Stock Market. These factors may result in higher price volatility and less market liquidity for the common stock.

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

Our common stock is currently trading at a price substantially below \$5.00 per share, subjecting trading in the stock to certain SEC rules requiring additional disclosures by broker-dealers. These rules generally apply to any non-NASDAQ equity security that has a market price share of less than \$5.00 per share, subject to certain exceptions (a "penny stock"). Such rules require the delivery, prior to any penny stock transaction, of a disclosure schedule explaining the penny stock market and the risks associated therewith and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and institutional or wealthy investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the 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 traded as low as \$0.29 per share and as high as \$0.87 per share during the 12-month period ended December 31, 2008. The market price of our common stock has been and is expected to continue to be highly volatile. Factors, including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by the company and by stockholders, and subsequent sale of common stock by the holders of warrants and options could have an adverse effect on the market price of our shares.

Some additional factors which could lead to the volatility of our common stock include:

- price and volume fluctuations in the stock market at large which do not relate to our operating performance;
- financing arrangements we may enter that require the issuance of a significant number of shares in relation to the number of shares currently outstanding;
  - public concern as to the safety of products that we or others develop; and
  - fluctuations in market demand for and supply of our products.

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

Generally, 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 12-month period ended December 31, 2008, was approximately 118,000 shares.

Some provisions of our organizational and governing documents may have the effect of deterring third parties from making takeover bids for control of our company or may be used to hinder or delay a takeover bid.

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

Because we will not pay dividends in the foreseeable future, 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.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

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 June 1, 2007 and ending on January 31, 2013, at a monthly base rent of approximately \$8,200 during 2009. 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. Although these facilities are adequate for our current needs, we may need to expand our leased space related to our radiopharmaceutical activities depending on the level of activities performed internally versus by third parties.

#### Item 3. Legal Proceedings

None.

#### Item 4. Submission of Matters to a Vote of Security Holders

None.



## PART II

## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock trades on the OTC Bulletin Board (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
<b>Fiscal Year 2008:</b>			
First Quarter	\$ 0.42	\$ 0.29	\$ 0.35
Second Quarter	0.87	0.34	0.68
Third Quarter	0.75	0.42	0.57
Fourth Quarter	0.68	0.45	0.57
<b>Fiscal Year 2007:</b>			
First Quarter	\$ 0.27	\$ 0.20	\$ 0.24
Second Quarter	0.32	0.19	0.31
Third Quarter	0.50	0.23	0.31
Fourth Quarter	0.35	0.25	0.29

As of March 16, 2009, we had approximately 790 holders of common stock of record.

We have not paid any dividends on our common stock and do not anticipate paying cash dividends on our common stock 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.

## 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), and have not been previously reported by us in periodic reports filed under the Securities Exchange Act of 1934 (the Exchange Act).

During 2008, an outside investor who received warrants to purchase our common stock in connection with a November 2003 financing exercised a total of 200,200 Series R warrants in exchange for issuance of 200,200 shares of our common stock, resulting in gross proceeds of \$56,056. In addition, certain outside investors who also received warrants to purchase our common stock in connection with the November 2003 financing exercised a total of 2,658,698 Series R warrants and 644,565 Series S warrants on a cashless basis in exchange for issuance of 1,289,990 shares of our common stock. The issuances of the shares to the investors were exempt from registration under Sections 4(2) and 4(6) of the Securities Act and Regulation D

During 2008, David C. Bupp, our President and CEO, who received warrants in connection with an April 2003 financing, exercised 375,000 Series Q warrants in exchange for issuance of 375,000 shares of our common stock, resulting in gross proceeds of \$48,750. In addition, an outside investor, who also received warrants in connection with an April 2003 financing, exercised 500,000 Series Q warrants in exchange for issuance of 500,000 shares of our

common stock, resulting in gross proceeds of \$65,000. During 2009 to date, Mr. Bupp exercised a portion of his outstanding Series Q warrants in exchange for issuance of 50,000 shares of our common stock, resulting in gross proceeds of \$25,000. The issuance of the warrants to Mr. Bupp and the outside investor were exempt from registration under Sections 4(2) and 4(6) of the Securities Act and Regulation D.

## Item 6. Selected Financial Data

Not applicable to smaller reporting companies.

## Item 7. 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-K. 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 1A of this Form 10-K, Risk Factors.

### The Company

Neoprobe Corporation is a biomedical technology company that provides innovative surgical and diagnostic products that enhance patient care. We currently market two lines of medical devices; our neoprobe® GDS 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, Lymphoseek® and RIGScan® CR, in advanced phases of clinical development. We are also exploring the development of our activated cellular therapy (ACT) technology for patient-specific disease treatment through our majority-owned subsidiary, Cira Biosciences, Inc. (Cira Bio).

### Executive Summary

This Executive Summary section contains a number of forward-looking statements, all of which are based on our 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 medical device product lines. We cannot assure you that we will achieve the volume of sales anticipated, or if achieved, that the margin on such sales will be adequate to produce positive operating cash flow. We continue to be optimistic about the longer-term potential for our proprietary, procedural-based technologies such as Lymphoseek and RIGS® (radioimmunoguided surgery); however, these technologies are not anticipated to generate any significant revenue for us during 2009. In addition, we cannot assure you that these products will ever obtain marketing clearance from the appropriate regulatory bodies.

We believe that the future prospects for Neoprobe continue to improve as we make progress in all of our key growth areas. Our development efforts during 2008 were focused primarily on support of Lymphoseek product development. However, we continued to modestly invest in our gamma detection device line related to product line expansion and innovation and to move our RIGS initiative forward with modest expenditures. Our efforts during 2008 resulted in the following research and investment milestone achievements:

- Initiated patient enrollment in a Phase 3 clinical study to evaluate the efficacy of Lymphoseek in patients with breast cancer or melanoma.
- Submitted a protocol design for a second Phase 3 clinical study to evaluate the efficacy of Lymphoseek as a sentinel lymph node tracing agent in patients with head and neck squamous cell carcinoma to the U.S. Food and Drug Administration (FDA) and the European Medicinal Evaluation Agency (EMA) and received a positive protocol assessment from EMA.

- Received a positive response on a regulatory pathway and a Phase 3 clinical trial design for RIGScan CR with regulatory authorities in the European Union (EU) under the scientific review process.
- Completed \$6 million in investments from Platinum-Montaur Life Sciences LLC (Montaur). The closings represented the second and third tranches of a total \$13 million investment received from Montaur since December of 2007. The third closing of the investment occurred following notification to Montaur of results from the first 135 lymph nodes tested in a Phase 3 clinical trial for Lymphoseek in patients with breast cancer or melanoma.
  - Introduced an enhanced neoprobe GDS gamma detection system control unit.
- Introduced a wireless version of a laparoscopic gamma detection probe based on Bluetooth® wireless technology.

#### Our Outlook for our Drug and Therapeutic Initiatives

The primary focus of our drug and therapeutic development efforts during 2008 centered on completing regulatory submissions of our successful Phase 2 clinical trial for Lymphoseek for patients with breast cancer or melanoma and on preparing for and initiating of Phase 3 clinical trial activities with Lymphoseek in similar patient populations. Lymphoseek is intended to be used in surgical procedures for the detection of cancer cells in lymph nodes in a variety of tumor types including breast, melanoma, prostate, gastric and colon cancers. If approved, Lymphoseek would be the first radiopharmaceutical specifically designed to target the sentinel lymph node(s) that may be predictive of the spread of cancer into the lymphatic system. We expect our drug-related development expenses to increase significantly for 2009 over 2008 as we conclude the first of two multi-center Phase 3 clinical evaluations of Lymphoseek, as we prepare to initiate the second of such Phase 3 trials and as we continue to support the drug manufacturing and validation activities related to supporting the potential marketing registration of Lymphoseek.

During 2008, we initiated patient enrollment in the first of the two phase 3 clinical studies to be conducted in patients with either breast cancer or melanoma. In March 2009, we announced that this first study had reached the accrual of 203 lymph nodes, the study's primary accrual objective. In the previous Phase 2 multi-center study of Lymphoseek, which was also conducted in patients with breast cancer or melanoma, an overall localization rate of 94% in lymph nodes was achieved in those patients where both a vital blue dye and Lymphoseek were used. A similar concordance rate of 94% was established by Neoprobe and FDA as the primary efficacy objective for the Phase 3 trial, NEO3-05. Based upon the intraoperative worksheets and preliminary pathology reports, we believe that the primary efficacy end-point of NEO3-05 has been achieved and no incidents related to drug safety have been reported in the Lymphoseek studies. Upon completion of a full analysis of the Phase 3 data, we will provide a complete update on the study results after all clinical data has been reviewed by our internal clinical team and external consultants. We expect full data will be available in the 2nd quarter of 2009.

In addition, we continue to prepare to commence a second Phase 3 study to be conducted in patients with head and neck squamous cell carcinoma. This second Phase 3 study is designed to validate Lymphoseek as a sentinel lymph node targeting agent. Our discussions with FDA and EMEA have also suggested that the Phase 3 trials will support an intended use of Lymphoseek in sentinel lymph node biopsy procedures. We believe such an indication, if approved, would be beneficial to the marketing and commercial adoption of Lymphoseek in the U.S. and EU. We plan to use the safety and efficacy results from the Phase 3 clinical evaluations of Lymphoseek, which will include sites in the EU, to support the drug registration application process in the EU as well as in the U.S. We received EMEA's consent to an open label Phase 3 trial in the third quarter of 2008 and began efforts during the fourth quarter to harmonize the trial approach with FDA. We plan to have approximately 25 participating institutions in the trial, which we hope will enable us to enroll patients at a fairly rapid rate. We have provided a number of the trial sites with the protocol and other supporting documentation and are awaiting clearances from the institutional review boards at a number of the participating institutions in order to commence patient enrollment. Our goal is to file the new drug application for Lymphoseek in early 2010; however, this will be dependent upon our ability to commence and successfully conclude the Phase 3 clinical studies in a timely fashion. Depending on the timing and outcome of the

FDA regulatory review cycle, we believe that Lymphoseek may be commercialized in late 2010 or early 2011. We cannot assure you, however, that this product will achieve regulatory approval, or if approved, that it will achieve market acceptance.

During 2008, we continued to make progress in advancing our RIGScan CR development program while incurring minimal research expenses. Our RIGS technology, which had been essentially inactive since failing to gain approval following our original license application in 1997, has been the subject of renewed interest due primarily to the analysis of survival data related to patients who participated in the original Phase 3 clinical studies that were completed in 1996. We believe our RIGScan progress took a significant step forward during 2008.

In July 2008, we initiated a scientific review of a Phase 3 trial design for RIGScan CR with EMEA and completed a pre-submission meeting; we received their decision on the scientific review of the RIGScan clinical program in October 2008. The scientific advice review process and EMEA response yielded a number of positive outcomes. First, we were able to present and to have accepted a proposal for the reactivation of the manufacturing of the biologic used in RIGScan CR and the radiolabeling of the product. Second, EMEA indicated all of the safety data previously generated in the RIGScan clinical trials was accepted by opinion; further, the opinion indicated that the historical safety data coupled with any prospective data would be sufficient to establish the safety parameters for RIGScan CR. Thirdly, the scientific advice opinion agreed with our assessment that RIGScan CR could be assessed in a mixed population of primary and recurrent/metastatic colorectal patients. This resulted in a proposed trial design involving approximately 380 patients in total with equal control and RIGS treatment groups. This number of patients is significantly less than had been considered previously. The participants in the trial would be randomized to either a control or RIGS treatment arm. Patients randomized to the RIGS arm would have their disease status evaluated at the end of their cancer surgery to determine the presence or absence of RIGS-positive tissue. Patients in both randomized arms would be followed to determine if patients with RIGS-positive status have a lower overall survival rate and/or a higher occurrence of disease recurrence. The hypothesis for the trial is based upon the data from the earlier NEO2-13 and NEO2-14 trial results. Finally, the advice opinion provided Neoprobe with the opportunity to seek a conditional marketing authorization (CMA) for RIGScan CR in the EU at various points in the development process, although there can be no assurance that if such a request is submitted, it would receive a favorable response. CMA procedures were established by EMEA in 2007, and provide a time specific marketing authorization for a product treating a life-threatening illness while additional development work is being completed. A CMA is subject to annual review by EMEA's governing body which ratified the RIGScan scientific advice.

We continue to believe it will be necessary for us to identify a development partner or an alternative funding source in order to prepare for and fund the pivotal clinical testing that will be necessary to gain marketing clearance for RIGScan CR. We believe the recent positive feedback from EMEA adequately clarifies the regulatory pathway in a fashion that will allow us to re-approach parties that we have talked to in the past as well as potential new parties. The development timeline for RIGScan CR is highly dependent on securing adequate financial support to move the project forward in a timely fashion in order to satisfy development diligence requirements. However, even if we are able to establish a development partnership or obtain funding arrangements on satisfactory terms, we believe it would take a minimum of 12 – 15 months following the restart of biologic production activities before a pivotal clinical trial could commence. Excluding the potential opportunity to seek a CMA, 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. We cannot assure you that we will be able to complete definitive agreements with a development partner or obtain financing to fund development of the RIGS technology, and do not know if such arrangements could be obtained on a timely basis on terms acceptable to us, or at all. We also cannot assure you that FDA or EMEA will clear our RIGS products for marketing or that any such products will be successfully introduced or achieve market acceptance.

We still hope to raise funds through our subsidiary, Cira Bio, to support the continued development of ACT; however, our fundraising efforts have thus far not been successful. We do not know if we will be successful in obtaining funding on terms acceptable to us, or at all. In the event we fail to obtain financing for Cira Bio, the technology rights for the oncology applications of ACT may revert back to Neoprobe and the technology rights for the viral and autoimmune applications may revert back to Cira LLC upon notice by either party.



## Medical Device Business Outlook

We believe our core gamma detection device business line will continue to achieve positive results in 2009. Our belief is based on continued interest in the research community in lymphatic mapping. Although numerous studies have examined the correlation between the sentinel node and the remaining axillary nodes, two large randomized multi-center trials ended about three years ago that will compare the long-term results of sentinel lymph node removal with full axillary node dissection. While both of these trials are now closed, we expect data from these studies may be published and/or presented in the near future. We expect the results from these clinical trials, when widely publicized, will have a further positive impact on helping us to penetrate the remaining market for breast cancer and melanoma. We believe that the surgical community will continue to adopt the sentinel lymph node biopsy (SLNB) application while a standard of care determination is still pending. We also believe that Lymphoseek, our lymphatic targeting agent, should it become commercially available, could significantly improve the adoption of SLNB in future years in areas beyond melanoma and breast cancer. To that end, we are supporting the clinical evaluation of Lymphoseek in human patients in a planned Phase 3 trial in head and neck squamous cell carcinoma and in ongoing Phase 1 trials in patients with either prostate or colon cancers.

We believe that most of the leading cancer treatment institutions in the U.S. and other major global markets have adopted SLNB and purchased gamma detection systems such as the neoprobe GDS. As a result, we may be reaching saturation within this segment of the market, except for a replacement sales market which we also believe is developing as devices introduced during the early years of lymphatic mapping begin to age over ten years. A decline in the adoption rate of SLNB or the development of alternative technologies by competitors may negatively impact our sales volumes, and therefore, revenues and net income in future years. In order to address the issue of potential saturation as well as to continue to provide our customers with the highest quality tools for performing SLNB, we have introduced several enhancements to our gamma device product line over the past few years and anticipate the launch of a higher energy gamma detection probe in mid- 2009.

Our gamma detection devices are distributed in most global markets by Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company. Under the terms of our distribution agreement with EES, the transfer prices we receive on product sales to EES are based on a fixed percentage of their end-customer average sales price (ASP), subject to a floor transfer price. Throughout their sales history, our products have generally 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. The end-customer ASP received by EES for our base gamma detection systems increased approximately 11% in 2008 as compared to 2007, due in part to the favorable impact of the exchange rate on our sales prices coupled with improved pricing on our neoprobe GDS system. While we continue to believe in the technical and user-friendly superiority of our products, the competitive landscape continues to evolve and current economic conditions present a number of challenges to the outlook for medical device sales. We may lose market share or experience price erosion and/or lower sales volumes as a result, any of which would have a direct negative impact on net income. If price erosion occurs to a greater extent in 2009, or if the U.S. Dollar gains significantly against the Euro, there is a risk associated with future sales prices of our gamma detection devices to EES that may erode some or all of the premium we received in prior years in excess of the floor price. However, in December 2007, Neoprobe and EES executed an amendment to the distribution agreement which extended the agreement through the end of 2013. The amendment modified certain terms of the agreement including increasing the percentage of EES' sales which Neoprobe receives by 15-20% and setting minimum performance requirements in order to maintain exclusivity.



We expect revenue from our medical device lines to continue to provide a strong revenue base during 2009 and for our device gross margins to improve based on changes in our underlying distribution agreements; however, it is difficult, given the potential impact of current economic conditions on medical device purchasing, to precisely estimate where overall revenues for 2009 may be. We expect to continue to incur modest development expenses to support our device product lines as we work with our marketing partners to expand our product offerings in the gamma detection device arena. During 2008, we significantly curtailed our financial support for our blood flow measurement products. We expect to continue to limit such expenditures in 2009. We expect that sales of our medical devices in 2009 will result in a net profit for these business lines in 2009, excluding the allocation of any corporate general and administrative costs. If we are unsuccessful in achieving adequate commercial sales from our medical device sales, our profitability outlook will be adversely affected and our business plan may need to be modified.

Primarily as a result of the significant development costs we expect to incur related to the continued clinical development of Lymphoseek, we do not expect to achieve operating profit during 2009. In addition, our net loss and loss per share will likely be significantly impacted by the non-cash interest expense we expect to record due to the accounting treatment for the derivative liabilities related to the convertible debt we issued in December 2007, and the beneficial conversion feature, warrants and derivative liabilities related to the convertible debt we issued in April 2008. We cannot assure you that our current or potential new products will be successfully commercialized, that we will achieve significant product revenues, or that we will achieve or be able to sustain profitability in the future.

#### Results of Operations

Revenue for 2008 increased to \$7.9 million from \$7.1 million in the prior year. The increase was primarily due to sales of our neoprobe GDS control units (launched during 2008) and wireless probes, offset by decreases in sales of the legacy versions of our gamma detection systems (i.e., neo2000 control units and corded probes) and of our blood flow measurement devices. In addition, we recognized revenue of \$172,000 related to research and development revenue from EES related to the development of a high energy probe recently introduced at a conference of the Society of Surgical Oncology.

Gross margins for 2008 increased to 62% as compared to 55% in 2007. The increase in gross margins was due to a combination of factors including research and development revenue from EES in 2008, a lower proportionate level of demonstration units placed in 2008 compared to 2007, increased unit sales and prices of gamma detection control units and increased unit sales and prices of wireless probes offset by a decrease in the percentage of ASP for wireless probes received by Neoprobe. The price increases we experienced in 2008 were due in part to the current favorable impact on our sales prices to EES of the Euro to U.S. Dollar exchange rate as well as improvement in prices in base currencies. Gross margins in 2008 and 2007 were also adversely affected by inventory impairments of \$26,000 and \$105,000, respectively, related to our Quantix products.

Results for 2008 also reflect an increase in research and development expenditures of \$1.6 million to \$4.5 million from \$2.9 million in 2007. The increase was primarily due to higher Lymphoseek development expenses related to conducting the Phase 3 clinical trials as well as increased activities related to RIGScan CR. Research and development costs were further increased by additional expenses related to investment in our gamma detection device line related to product line expansion and innovation, offset by cost savings related to curtailing our activities associated with the blood flow measurement line. Consolidated selling, general and administrative expenses increased to \$3.4 million in 2008 from \$2.8 million in 2007.

Net Sales and Margins. Net sales, comprised primarily of sales of our gamma detection systems, increased \$590,000, or 8%, to \$7.7 million during 2008 from \$7.1 million in 2007. Gross margins on net sales increased to 62% of net sales for 2008 compared to 55% of net sales for 2007.

The wireless innovations we have made to both the probes and control units in our gamma detection device product line over the last two years have positively impacted our sales in 2008. Overall, the increase in net sales was the result of increased gamma detection device sales of \$491,000, increased gamma detection device extended service contract revenue of \$145,000 and increased gamma detection device service-related revenue of \$9,000, offset by decreased blood flow measurement device sales of \$55,000. Increased unit sales of our control units and wireless probes were partially offset by decreased unit sales of corded probes. Increased unit prices of our control units and corded probes were partially offset by decreased unit prices of our wireless probes due to a decrease in the percentage of ASP received by Neoprobe offsetting an overall increase in ASP for wireless probes.

The increase in gross margins on net product sales was due to a combination of factors including a lower proportionate level of demonstration units placed in 2008 compared to 2007, increased unit sales and prices of gamma detection control units and increased unit sales and prices of wireless probes offset by a decrease in the percentage of ASP for wireless probes received by Neoprobe. The price increases we experienced in 2008 were due in part to the current favorable impact on our sales prices to EES of the Euro to U.S. Dollar exchange rate. Gross margins in 2008 and 2007 were also adversely affected by inventory impairments of \$26,000 and \$105,000, respectively, related to our Quantix products.

**Research and Development Expenses.** Research and development expenses increased \$1.6 million, or 57%, to \$4.5 million during 2008 from \$2.9 million in 2007. Research and development expenses in 2008 included approximately \$3.3 million in drug and therapy product development costs, \$949,000 in gamma detection device development costs, and \$219,000 in product design and support activities for the Quantix products. This compares to expenses of \$1.8 million, \$680,000 and \$359,000 in these segment categories in 2007. The changes in each category were primarily due to (i) increased clinical activities related to Lymphoseek due to costs of conducting the Phase 3 clinical trials in 2008 being higher than costs of conducting the Phase 2 clinical trials in 2007, as well as increased activities related to RIGScan CR, (ii) development of our neoprobe GDS control units and various probes in 2008, and (iii) decreased product refinement activities related to our Quantix devices, respectively.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses increased \$575,000, or 20%, to \$3.4 million during 2008 from \$2.8 million in 2007. The net difference was due primarily to increases in investor relations expenses, professional services and personnel-related expenses.

**Other Income (Expenses).** Other expenses, net decreased \$1.2 million to \$2.1 million during 2008 from \$3.3 million in 2007. Interest expense, primarily related to the convertible debt agreements we completed in December 2004, July 2007, December 2007 and April 2008, decreased \$539,000 to \$1.7 million during 2008 from \$2.3 million in 2007. Of this interest expense, \$706,000 and \$1.4 million in 2008 and 2007, respectively, was non-cash in nature related to the amortization of debt issuance costs and discounts resulting from the warrants, beneficial conversion features and derivative liabilities related to the convertible debt. Interest expense in 2007 also included an adjustment to non-cash interest which was recorded in the third quarter of 2007. During the fourth quarter of 2007, we also recorded debt extinguishment charges of \$860,000 related to modification of the terms of a convertible debt agreement with our CEO. In addition, during 2008 and 2007, we recorded \$451,000 and \$248,000, respectively, of increases in derivative liabilities resulting from the accounting treatment for the convertible note agreements we executed in December 2007 and April 2008 and the related warrants to purchase our common stock, which contained certain provisions that resulted in their being treated as derivative instruments.

#### Liquidity and Capital Resources

Cash and investment balances increased to \$4.1 million at December 31, 2008 from \$1.5 million at December 31, 2007. The net increase was primarily derived from proceeds from new convertible debt and the issuance of preferred stock during 2008, offset by cash used to service our outstanding debt and to fund our operations, mainly for research and development activities. The current ratio increased to 3.1:1 at December 31, 2008 from 2.1:1 at December 31, 2007. The increase in the current ratio was primarily due to the increase in cash and investment balances.

**Operating Activities.** Cash used in operations increased \$1.7 million to \$3.0 million during 2008 compared to \$1.3 million in 2007.

Accounts receivable remained steady at \$1.6 million at December 31, 2008 and 2007. We expect overall receivable levels will continue to fluctuate during 2009 depending on the timing of purchases and payments by EES.

Inventory levels decreased to \$962,000 at December 31, 2008 as compared to \$1.2 million at December 31, 2007. Gamma detection device materials decreased as materials were converted into finished devices. Blood flow measurement device materials decreased primarily as a result of inventory impairments of \$26,000. Blood flow measurement finished device inventories also decreased as a result of sales. During the third quarter of 2008 we recorded an inventory adjustment charge related to our Lymphoseek product of \$153,000 due to changes in our projections of the probability of future commercial use of the previously capitalized costs. These decreases were offset by increased gamma detection device finished goods due primarily to the timing of production runs and sales to EES. We expect inventory levels to increase during 2009 primarily as a result of production of a commercial lot of Lymphoseek.

Investing Activities. Cash used in investing activities increased \$579,000 to \$627,000 during 2008 compared to \$48,000 during 2007. We purchased \$690,000 of available-for-sale securities during 2008, \$196,000 of which also matured during 2008. Capital expenditures during 2008 were primarily for software, computers, production tools and equipment and laboratory equipment. Capital expenditures during 2007 were primarily for production tools and equipment and software. We expect our overall capital expenditures for 2009 will be higher than in 2008 as we prepare for the commercial production of Lymphoseek.

Financing Activities. Cash provided by financing activities increased \$5.3 million to \$5.7 million during 2008 compared to \$351,000 during 2007. Proceeds from the issuance of preferred stock were \$3.0 million during 2008. Proceeds from the issuance of common stock were \$232,000 and \$1.9 million during 2008 and 2007, respectively. Payments of stock issuance costs were \$181,000 and \$23,000 during the same periods. Proceeds from the issuance of new notes payable were \$3.0 and \$8.0 million during 2008 and 2007, respectively. Payments of notes payable were \$158,000 and \$8.3 million during 2008 and 2007, respectively. Payments of debt issuance costs were \$200,000 and \$565,000 during the same periods. Payments for the repurchase of warrants related to debt extinguished in 2007 totaled \$675,000.

In December 2004, we completed a private placement of four-year convertible promissory notes in an aggregate principal amount of \$8.1 million under a Securities Purchase Agreement 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 (collectively, the Great Point Funds). The notes originally bore interest at 8% per annum and were due on December 13, 2008. As part of the original transaction with the Great Point Funds, we issued the investors Series T warrants to purchase 10,125,000 shares of our common stock at an exercise price of \$0.46 per share, expiring in December 2009. In connection with this financing, we also issued Series U warrants to purchase 1,600,000 shares of our common stock to the placement agents, containing substantially the same terms as the warrants issued to the investors.

In November 2006, we amended the Securities Purchase Agreement and modified several of the key terms in the related notes, including the interest rate which was increased to 12% per annum, and modified the maturity of the notes to provide for a series of scheduled payments due on approximately six month intervals through January 7, 2009. We were also required to make additional mandatory repayments of principal to the Great Point Funds under certain circumstances. In exchange for the increased interest rate and accelerated principal repayment schedule, the note holders eliminated the financial covenants under the original notes and eliminated certain conversion price adjustments from the original notes related to sales of equity securities by Neoprobe. During 2007, we made scheduled principal payments and mandatory repayments totaling \$2.4 million. We made no payments during 2008 due to the complete repayment of all outstanding obligations under the Replacement Series A Promissory Notes in December 2007.



In December 2006, we entered into a common stock purchase agreement with Fusion Capital, an Illinois limited liability company, to sell \$6.0 million of our common stock to Fusion Capital over a 24-month period which ended on November 21, 2008. Through November 21, 2008, we sold to Fusion Capital under the agreement 7,568,671 shares for proceeds of \$1.9 million. In December 2008, we entered into an amendment to the agreement which gave us a right to sell an additional \$6.0 million of our common stock to Fusion Capital before March 1, 2011, along with the \$4.1 million of the unsold balance of the \$6.0 million we originally had the right to sell to Fusion Capital under the original agreement. After giving effect to this amendment, the remaining aggregate amount of our common stock we can sell to Fusion Capital is \$10.1 million. In respect of sales to Fusion Capital that we may make in the future under the amended agreement, we have reserved authorized a total of 10,654,000 shares of our common stock.

In December 2006, we issued to Fusion Capital 720,000 shares of our common stock as a commitment fee upon execution of the original agreement. As sales of our common stock were made under the original agreement, we issued an additional 234,000 shares of our common stock to Fusion Capital as an additional commitment fee. In connection with entering into the amendment, we issued an additional 360,000 shares in consideration for Fusion Capital's entering into the amendment. Also, as an additional commitment fee, we have agreed to issue to Fusion Capital an additional 486,000 shares of our common stock pro rata as we sell the first \$4.1 million of our common stock to Fusion Capital under the amended agreement.

In July 2007, David C. Bupp, our President and CEO, and certain members of his family (the Bupp Investors) purchased a \$1.0 million convertible note (the Bupp Note) and warrants. The note bears interest at 10% per annum, had an original term of one year and is repayable in whole or in part with no penalty. The note is convertible into shares of our common stock at a price of \$0.31 per share, a 25% premium to the average closing market price of our common stock for the 5 days preceding the closing of the transaction. As part of this transaction, we issued the investors 500,000 Series V warrants to purchase our common stock at an exercise price of \$0.31 per share, expiring in July 2012.

In December 2007, we entered into a Securities Purchase Agreement (SPA) with Montaur, pursuant to which we issued Montaur a 10% Series A Convertible Senior Secured Promissory Note in the principal amount of \$7,000,000, due December 26, 2011 (the Series A Note) and a five-year Series W warrant to purchase 6,000,000 shares of our common stock, \$.001 par value per share, at an exercise price of \$0.32 per share. Montaur may convert \$3.5 million of the Series A Note into shares of our common stock at the conversion price of \$0.26 per share. The SPA also provided for two further tranches of financing, a second tranche of \$3 million in exchange for a 10% Series B Convertible Senior Secured Promissory Note along with a five-year Series X warrant to purchase shares of our common stock, and a third tranche of \$3 million in exchange for 3,000 shares of our 8% Series A Cumulative Convertible Preferred Stock and a five-year Series Y warrant to purchase shares of our common stock. Closings of the second and third tranches were subject to the satisfaction by the Company of certain milestones related to the progress of the Phase 3 clinical trials of our Lymphoseek radiopharmaceutical product.

In April 2008, following receipt by the Company of clearance by FDA to commence a Phase 3 clinical trial for Lymphoseek in patients with breast cancer or melanoma, we amended the SPA related to the second tranche and issued Montaur a 10% Series B Convertible Senior Secured Promissory Note in the principal amount of \$3,000,000, also due December 26, 2011 (the Series B Note, and hereinafter referred to collectively with the Series A Note as the Montaur Notes), and a five-year Series X warrant to purchase 8,333,333 shares of our common stock at an exercise price of \$0.46 per share. Montaur may convert the Series B Note into shares of our common stock at the conversion price of \$0.36 per share. Provided we have satisfied certain conditions stated therein, we may elect to make payments of interest due under the Montaur Notes in registered shares of our common stock. If we choose to make interest payments in shares of common stock, the number of shares of common stock to be applied against any such interest payment will be determined by reference to the quotient of (a) the applicable interest payment divided by (b) 90% of the average daily volume weighted average price of our common stock on the OTCBB (or national securities

exchange, if applicable) as reported by Bloomberg Financial L.P. for the five days upon which our common stock is traded on the OTCBB immediately preceding the date of the interest payment.

In December 2008, after we obtained 135 vital blue dye lymph nodes from patients who had completed surgery and the injection of the drug in a Phase 3 clinical trial of Lymphoseek in patients with breast cancer or melanoma, we issued Montaur 3,000 shares of our 8% Series A Cumulative Convertible Preferred Stock (the Preferred Stock) and a five-year Series Y warrant (hereinafter referred to collectively with the Series W warrant and Series X warrant as the Montaur Warrants) to purchase 6,000,000 shares of our common stock, at an exercise price of \$0.575 per share, also for an aggregate purchase price of \$3,000,000. Montaur may convert each share of the Preferred Stock into a number of shares of our common stock equal to the quotient of (a) the Liquidation Preference Amount of the shares of Preferred Stock by (b) the Conversion Price. The "Liquidation Preference Amount" for the Preferred Stock is \$1,000 and the "Conversion Price" of the Preferred Stock was set at \$0.50 on the date of issuance, thereby making the shares of Preferred Stock convertible into an aggregate 6,000,000 shares of our common stock, subject to adjustment as described in the Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series A 8% Cumulative Convertible Preferred Stock. We may elect to pay dividends due to Montaur on the shares of Preferred Stock in registered shares of our common stock. The number of shares of common stock to be applied against any such dividend payment will be determined by reference to the quotient of (a) the applicable dividend payment by (b) the average daily volume weighted average price of our common stock on the OTCBB (or national securities exchange, if applicable) as reported by Bloomberg Financial L.P. for the five days upon which our common stock is traded on the OTCBB immediately preceding the date of the dividend payment.

In connection with the Montaur SPA, the term of the \$1.0 million Bupp Note was extended to December 27, 2011, one day following the maturity date of the Montaur Notes. In consideration for the Bupp Investors' agreement to extend the term of the Bupp Note pursuant to an Amendment to the Bupp Purchase Agreement, dated December 26, 2007, we agreed to provide security for the obligations evidenced by the Amended 10% Convertible Note in the principal amount of \$1,000,000, due December 31, 2011, executed by Neoprobe in favor of the Bupp Investors (the Amended Bupp Note), under the terms of a Security Agreement, dated December 26, 2007, by and between Neoprobe and the Bupp Investors (the Bupp Security Agreement). This security interest is subordinate to the Security interest of Montaur. As further consideration for extending the term of the Bupp Note, we issued the Bupp Investors Series V warrants to purchase 500,000 shares of our common stock at an exercise price of \$0.32 per share, expiring in December 2012. The Amended Bupp Note had an outstanding principal amount of \$1.0 million on December 31, 2008, and an outstanding principal amount of \$1.0 million as of March 16, 2009. During 2008, we paid no amount of the outstanding principal, and paid \$100,000 in interest due under the Amended Bupp Note.

We applied \$5,725,000 from the proceeds of our issuance of the Series A Note and Series W warrant to the complete repayment of our outstanding obligations under the Replacement Series A Convertible Promissory Notes issued to the Great Point Funds and David C. Bupp as of November 30, 2006, pursuant to the Securities Purchase Agreement, dated as of December 13, 2004, by and among Neoprobe, the Great Point Funds and Mr. Bupp, as amended by the Amendment dated as of November 30, 2006 (the Amended GPP Purchase Agreement). We applied an additional \$675,000 from the proceeds of our issuance of the Series A Note and Series W warrant to the redemption of Series T warrants to purchase 10,000,000 shares of our common stock at an exercise price of \$0.46 per share, issued to the Great Point Funds pursuant to the Amended GPP Purchase Agreement. In connection with the consummation of the Montaur SPA and amendment of the Bupp Purchase Agreement, Mr. Bupp agreed to the cancellation of Series T warrants to purchase 125,000 shares of our common stock at an exercise price of \$0.46 per share, issued to Mr. Bupp pursuant to the Amended GPP Purchase Agreement without additional consideration to Mr. Bupp other than discussed above.



Our future liquidity and capital requirements will depend on a number of factors, including our ability to expand 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 international regulatory bodies, and intellectual property protection. Our most significant near-term development priority is to finalize the results from the first of two Phase 3 clinical trials for Lymphoseek and to initiate the second Phase 3 trial. We believe our current funds and available capital resources will be adequate to complete our Lymphoseek development efforts and sustain our operations at planned levels through 2009. We are also in the process of determining the total development cost necessary to commercialize RIGScan CR but believe that it will require commitments of between \$3 million to \$5 million to restart manufacturing and other activities necessary to prepare for the Phase 3 clinical trial contemplated in the recent EMEA scientific advice response. We may be able to raise additional funds through a stock purchase agreement with Fusion Capital to supplement our capital needs. However, the extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Specifically, Fusion Capital does not have the right or the obligation to purchase any shares of our common stock on any business day that the market price of our common stock is less than \$0.20 per share. We cannot assure you that we will be successful in raising additional capital through Fusion Capital or any other sources at terms acceptable to the Company, or at all. We also cannot assure you that we will be able to successfully commercialize products, that we will achieve significant product revenues from our current or potential new products or that we will achieve or sustain profitability in the future.

#### Recent Accounting Developments

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS No. 157 does not require any new fair value measurements. SFAS No. 157 was initially effective for Neoprobe beginning January 1, 2008. In February 2008, the FASB approved the issuance of FASB Staff Position (FSP) FAS 157-2. FSP FAS 157-2 allows entities to electively defer the effective date of SFAS No. 157 until January 1, 2009 for nonfinancial assets and nonfinancial liabilities except those items recognized or disclosed at fair value on at least an annual basis. We will apply the fair value measurement and disclosure provisions of SFAS No. 157 to nonfinancial assets and liabilities effective January 1, 2009. The application of such is not expected to be material to our consolidated results of operations or financial condition.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities – Including an Amendment of FASB Statement No. 115 (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value at specified election dates. Most of the provisions of SFAS No. 159 apply only to entities that elect the fair value option. However, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. The fair value option established by SFAS No. 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method, is irrevocable (unless a new election date occurs), and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We adopted SFAS No. 159 as required on January 1, 2008; however, we did not elect to measure any of our currently outstanding financial instruments using the fair value option outlined in SFAS No.

159. As such, the adoption of SFAS No. 159 did not have any impact on our consolidated results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations (SFAS No. 141(R)). SFAS No. 141(R) retains the fundamental requirements of the original pronouncement requiring that the acquisition method (formerly called the purchase method) of accounting be used for all business combinations and for an acquirer to be identified for each business combination. SFAS No. 141(R) defines the acquirer as the entity that obtains control of one or more businesses in the business combination, establishes the acquisition date as the date that the acquirer achieves control and requires the acquirer to recognize the assets and liabilities assumed and any noncontrolling interest at their fair values as of the acquisition date. SFAS No. 141(R) requires, among other things, that the acquisition-related costs be recognized separately from the acquisition. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and is required to be adopted by Neoprobe beginning January 1, 2009. The effect the adoption of SFAS No. 141(R) will have on us will depend on the nature and size of acquisitions we complete after we adopt SFAS No. 141(R), if any.

Also in December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements – an Amendment of ARB No. 51 (SFAS No. 160). SFAS No. 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of ARB No. 51's consolidation procedures for consistency with the requirements of SFAS No. 141(R), Business Combinations. SFAS No. 160 is effective for fiscal years and interim periods within those fiscal years beginning on or after December 15, 2008, and is required to be adopted by Neoprobe beginning January 1, 2009. Earlier adoption is prohibited. SFAS No. 160 shall be applied prospectively as of the beginning of the fiscal year in which it is adopted, except for the presentation and disclosure requirements. The presentation and disclosure requirements shall be applied retrospectively for all periods presented. We do not expect the adoption of SFAS No. 160 to have a material effect on our consolidated results of operations or financial condition.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force (EITF) on EITF Issue No. 07-1, Accounting for Collaborative Arrangements. EITF Issue No. 07-1 focuses on defining a collaborative arrangement as well as the accounting for transactions between participants in a collaborative arrangement and between the participants in the arrangement and third parties. The EITF concluded that both types of transactions should be reported in each participant's respective income statement. EITF Issue No. 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and should be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. We do not expect EITF Issue No. 07-1 to have a material effect on our consolidated results of operations or financial condition.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement No. 133 (SFAS No. 161). SFAS No. 161 amends and expands the disclosure requirements of Statement No. 133 to provide a better understanding of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for, and their effect on an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for fiscal years beginning after November 15, 2008. We are currently evaluating the impact that the adoption of SFAS No. 161 will have on our derivative disclosures.

In June 2008, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-5, Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock. EITF Issue No. 07-5 clarifies the determination of whether equity-linked instruments (or embedded features), such as our convertible notes or warrants to purchase our common stock, are considered indexed to our own stock, which would qualify as a scope exception under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. EITF Issue No. 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. We are currently evaluating the impact that the adoption of EITF Issue No. 07-5

will have on our consolidated financial statements. If we determine that the provisions of EITF Issue No. 07-5 are applicable to our financial instruments, we currently estimate that the adoption of EITF Issue No. 07-5 will result in a cumulative effect adjustment of approximately \$3.9 million that would be recorded as additional accumulated deficit during the first quarter of 2009 as well as the disclosure of additional derivative liabilities in our balance sheet in future reports.

## 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 measurement products constituted approximately 4% of total revenues for 2008. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a common carrier. We generally recognize sales revenue related to sales of our products when the products are shipped and the earnings process has been completed. 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. Our customers have no right to return products purchased in the ordinary course of business.

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.

We also generate revenue from the service and repair of out-of-warranty products. Fees charged for service and repair on products not covered by an extended service agreement are recognized on completion of the service process when the serviced or repaired product has been returned to the customer. Fees charged for service or repair of products covered by an extended warranty agreement are deferred and recognized as revenue ratably over the life of the extended service agreement.

**Use of Estimates.** The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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:

- **Stock-Based Compensation.** We account for stock-based compensation in accordance with SFAS No. 123(R), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their estimated fair values. Compensation cost arising from stock-based awards is recognized as expense using the straight-line method over the vesting period. We use the Black-Scholes option pricing model to value share-based payments. The valuation assumptions used have not changed from those used under SFAS No. 123.
- **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, regulations regarding use and shelf-life, product recalls and variation in product utilization all impact the estimates related to excess and obsolete inventory.

- **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. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. As of December 31, 2008, the most significant long-lived assets on our balance sheet relate to assets recorded in connection with the acquisition of CardioSonix. The recoverability of these assets is based on the financial projections and models related to the future sales success of CardioSonix' products. 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.
- **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.
- **Fair Value of Derivative Liabilities.** We account for derivatives in accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, which provides accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are required to be bifurcated from the debt instrument and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value. In accordance with SFAS No. 133, the conversion option and two put options embedded in the Series A Note issued in December 2007 were considered derivative instruments and were required to be bifurcated from the debt instrument and accounted for separately. In addition, in accordance with SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, the Series W warrant issued in connection with the Series A Note was accounted for as a liability due to the existence of certain provisions in the instrument. As a result, we recorded a total aggregate derivative liability of \$2.6 million on the date of issuance of the note. The fair value of the Series W warrant was determined using the Black-Scholes option pricing model. Changes in the fair value of the derivative liabilities are recorded in the consolidated statement of operations. As of December 31, 2007, the derivative liabilities had a fair value of \$1.60 million and \$1.25 million for the conversion and put options and the warrants, respectively.

On March 14, 2008, Neoprobe and Montaur executed amendments to the Series A Note and the Series W warrant. The amendments eliminated certain minor cash-based penalty provisions in the Series A Note and Series W warrant which entitled the holders to different compensation than our common shareholders under certain circumstances and qualifying Triggering Events. The provisions that were eliminated and/or modified were the provisions that led to the derivative accounting treatment for the embedded conversion option in the Series A Note and the Series W warrant. Because the value of our stock increased between December 31, 2007, our year end, and March 14, 2008, the effect of marking the conversion option and warrant liabilities to "market" at March 14, 2008 resulted in an increase in the estimated fair value of the conversion option and warrant liabilities of \$381,000 which was recorded as non-cash expense during the first quarter of 2008. The estimated fair value of the conversion option and warrant liabilities of \$2.9 million was reclassified to additional paid-in capital during the first quarter of 2008. The effect of marking the put option liabilities related to the Series A Note to "market" at March 31, June 30, September 30, and December 31, 2008 resulted in a net increase in the estimated fair value of the put option liabilities of \$51,000 which was recorded as non-cash expense during 2008. The estimated fair value of the put option liabilities related to the Series A Note of \$360,000 remained classified as derivative liabilities as of December 31, 2008.





The two put options embedded in the Series B Note issued in April 2008 were also considered derivative instruments and were required to be bifurcated from the debt instrument and accounted for separately. The fair value of the bifurcated put options was approximately \$258,000 on the date of issuance. Changes in the fair value of the derivative liabilities are recorded in the consolidated statement of operations. The effect of marking the put option liabilities related to the Series B Note to "market" at June 30, September 30, and December 31, 2008 resulted in a net increase in the estimated fair value of the put option liabilities of \$20,000 which was recorded as non-cash expense during 2008. The estimated fair value of the put option liabilities related to the Series B Note of \$277,000 remained classified as derivative liabilities as of December 31, 2008.

The put option embedded in the Series A Convertible Preferred Stock issued in December 2008 was also considered a derivative instrument and was required to be bifurcated from the equity instrument and accounted for separately. The fair value of the bifurcated put option was approximately \$216,000 on the date of issuance. Changes in the fair value of the derivative liability are recorded in the consolidated statement of operations. The estimated fair value of the put option liability related to the Preferred Stock of \$216,000 remained classified as a derivative liability as of December 31, 2008.

Our accounting for the financial instruments discussed above will likely be affected by the outcome of our determination of whether the provisions of EITF Issue No. 07-5 are applicable to these instruments.

#### Other Items Affecting Financial Condition

At December 31, 2008, we had deferred tax assets in the U.S. related to net operating tax loss carryforwards and tax credit carryforwards of approximately \$32.0 million and \$4.8 million, respectively, available to offset or reduce future income tax liabilities, if any, through 2028. 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 and are therefore fully reserved in our financial statements.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to smaller reporting companies.

#### Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, and the related notes, together with the report of BDO Seidman, LLP dated March 27, 2009, are set forth at pages F-1 through F-32 attached hereto.

#### Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A(T). Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized, and reported within the specified time periods. As a part of these controls, our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the company are being made only in accordance with authorization of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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 Exchange Act) as of December 31, 2008. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on our 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 and effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all errors and all improper conduct. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute assurance that the objectives of the control systems are met. Further, a design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments and decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons, or by management override of the control. Further, the design of any system of controls is also based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations of a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.



### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to management and the Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework. Based on our assessment we believe that, as of December 31, 2008, our internal control over financial reporting is effective based on those criteria.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report on Form 10-K.

### Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2008, there were no changes in our internal control over financial reporting that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### Item 9B. Other Information.

None.

### PART III

#### Item 10. Directors, Executive Officers and Corporate Governance

##### Directors

##### Directors whose terms continue until the 2009 Annual Meeting:

Kirby I. Bland, M.D., age 67, 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.

Gordon A. Troup, age 55, has served as a director of our Company since July 2008, Mr. Troup served as President of the Nuclear Pharmacy Services business at Cardinal Health, Inc. (Cardinal Health), a multinational medical products and services company, from January 2003 until his retirement in December 2007. Mr. Troup joined Cardinal Health in 1990 and was appointed Group President of Pharmaceutical Distribution and Specialty Distribution Services in 1999. Prior to joining Cardinal Health, Mr. Troup was employed for 10 years by American Hospital Supply Corporation and 3 years by Zellerbach Paper, a Mead Company. Mr. Troup has a B.S. degree in Business Management from San Diego State University. Mr. Troup is a member of several national healthcare trade organizations and is active in a number of not-for-profit organizations.

J. Frank Whitley, Jr., age 66, 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 is also involved with several not-for-profit health care organizations, serving as a member of their Boards of Trustees and/or Committees of the Board. Mr. Whitley has a B.S. degree in Mathematics from Lamar State College of Technology.

##### Directors whose terms continue until the 2010 Annual Meeting:

Reuven Avital, age 57, 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 board member of a number of privately-held Israeli companies, two 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 a board member of 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 59, 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 and retail banking operations throughout Central Ohio. Mr. Bupp has a B.A. degree in Economics from Ohio Wesleyan University. Mr. Bupp also completed a course of study at Stonier Graduate School of Banking at Rutgers University.

Directors whose terms continue until the 2011 Annual Meeting:

Carl J. Aschinger, Jr., age 70, has served as a director of our Company since June 2004 and as Chairman of the Board since July 2007. Mr. Aschinger is the Chairman of CSC Worldwide (formerly 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 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.

Owen E. Johnson, M.D., age 68, has served as a director of our Company since July 2007. Prior to his retirement in December 2006, Dr. Johnson served as Vice President and Senior Medical Director of UnitedHealthcare of Ohio, Inc. (UHC), a subsidiary of UnitedHealth Group, where he was involved in a number of roles and activities including new technology assessment and reimbursement establishment. During 2007, Dr. Johnson rejoined UnitedHealth Networks, a subsidiary of UnitedHealth Group, as Medical Director for their cardiac line of service. Dr. Johnson has also served on the Board and on numerous Committees of UHC as well as other related organizations. Prior to joining UHC, Dr. Johnson held several hospital appointments with Riverside Methodist Hospital in Columbus, Ohio. Dr. Johnson has also been active in numerous professional, fraternal and community organizations in the Columbus, Ohio area.

Fred B. Miller, age 69, 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.

## 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	48	Vice President, Manufacturing Operations
Rodger A. Brown	58	Vice President, Regulatory Affairs and Quality Assurance
Frederick O. Cope, Ph.D.	62	Vice President, Pharmaceutical Research and Clinical Development
Brent L. Larson	45	Vice President, Finance; Chief Financial Officer; Treasurer and Secretary
Douglas L. Rash	65	Vice President, Marketing

Anthony K. Blair has served as Vice President, Manufacturing Operations of our Company since July 2004. 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.

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 Regulatory Affairs/Quality Assurance 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.

Frederick O. Cope, Ph.D. has served as Vice President, Pharmaceutical Research and Clinical Development of our Company since February 2009. Prior to accepting this position with the Company, Dr. Cope served as the Assistant Director for Research and Head of Program Research Development for The Ohio State University Comprehensive Cancer Center, The James Cancer Hospital and The Richard J. Solove Research Institute, from April 2001 to February 2009. Dr. Cope is also active in a number of professional and scientific organizations such as serving as an Ad Hoc Member of the FDA Scientific Advisory Panel and a member of Emory University's Scientific Advisory Board. Dr. Cope received his BSc from the Delaware Valley College of Science and Agriculture, his MS from Millersville University of Pennsylvania and his Ph.D. from the University of Connecticut.

Brent L. Larson has served as Vice President, Finance, Chief Financial Officer and Treasurer of our Company since February 1999 and as Secretary since 2003. 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.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and greater than 10% stockholders, to file reports of ownership and changes in ownership of our securities with the Securities and Exchange Commission. Copies of the reports are required by SEC regulation to be furnished to us. Based on our review of these reports and written representations from reporting persons, we believe that all reporting persons complied with all filing requirements during the fiscal year ended December 31, 2008.

#### Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to our directors, officers and all employees. The code of business conduct and ethics is posted on our website at [www.neoprobe.com](http://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

The Audit Committee of the Board of Directors selects our independent public accountants with whom the Audit Committee reviews the scope of audit and non-audit assignments and related fees, the accounting principles that we use in financial reporting, and the internal controls over financial reporting identified by the independent accountants as a basis for designing their audit procedures. The members of our Audit Committee are: Fred B. Miller (Chairman), Reuven Avital, Gordon A. Troup, and J. Frank Whitley, Jr., each of whom is "independent" under the Nasdaq rules referenced below in Part III, Item 13 of this Form 10-K. The Board of Directors has determined that Fred B. Miller meets the requirements of an "audit committee financial expert" as set forth in Section 407(d)(5) of Regulation S-K promulgated by the SEC. The Audit Committee held five meetings in fiscal 2008.

## Item 11. 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 two highest paid executive officers during the last fiscal year (the Named Executives) for the last two fiscal years.

Name and Principal Position	Year	Salary	(a)	(b)	(c)	(d)	Total Compensation
			Bonus	Option Awards	Restricted Stock Awards	All Other Compensation	
Anthony K. Blair Vice President, Manufacturing Operations	2008	\$ 150,000	\$ 15,700	\$ 10,827	\$ 8,975	\$ 4,676	\$ 190,178
	2007	134,000	19,125	8,550	-	3,887	165,562
David C. Bupp President and Chief Executive Officer	2008	\$ 325,000	\$ 40,000	\$ 43,875	\$ 53,850	\$ 7,208	\$ 469,933
	2007	305,000	60,000	51,808	-	8,398	425,206
Brent L. Larson Vice President, Finance and Chief Financial Officer	2008	\$ 177,000	\$ 15,000	\$ 9,677	\$ 8,975	\$ 5,442	\$ 216,094
	2007	170,000	19,125	10,184	-	4,896	204,205

(a) Bonuses, if any, have been disclosed for the year in which they were earned (i.e., the year to which the service relates).

(b) Amount represents the dollar amount recognized for financial statement reporting purposes in accordance with SFAS No. 123(R). Assumptions made in the valuation of stock option awards are disclosed in Note 1(o) of the Notes to the Consolidated Financial Statements in this Form 10-K.

(c) Amount represents the dollar amount recognized for financial statement reporting purposes in accordance with SFAS No. 123(R). Assumptions made in the valuation of restricted stock awards are disclosed in Note 1(o) of the Notes to the Consolidated Financial Statements in this Form 10-K.

(d) Amount represents life insurance premiums paid during the fiscal year for the benefit of the Named Executives and matching contributions under the Neoprobe Corporation 401(k) Plan (the Plan). 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 5 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 qualifies 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.

## Compensation of Mr. Bupp

Employment Agreement. David C. Bupp is employed under a 12-month employment agreement effective January 1, 2009. The employment agreement provides for an annual base salary of \$335,000.

The Board of Directors and/or the Compensation, Nominating and Governance (CNG) Committee will, on an annual basis, review the performance of our Company and of Mr. Bupp and may 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 CNG Committee that covers the executive officers of the Company generally. For the calendar year ending December 31, 2009, the CNG Committee has determined that the maximum bonus payment to Mr. Bupp will be \$90,000.

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

- by the 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);
  - by the expiration of the term of Mr. Bupp's employment agreement; or
- by the resignation of Mr. Bupp because his title, authority, responsibilities, salary, bonus opportunities or benefits have materially diminished, a material adverse change in his working conditions has occurred, his services are no longer required in light of the Company's business plan, or we breach the agreement;

then, Mr. Bupp will be paid a severance payment of \$762,500 (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).

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

- the acquisition, directly or indirectly, by a person (other than our Company, an employee benefit plan established by the Board of Directors, or a participant in a transaction approved by the Board of Directors for the principal purpose of raising additional capital) of beneficial ownership of 30% or more of our securities with voting power in the next meeting of holders of voting securities to elect the directors;
- a majority of the Directors elected at any meeting of the holders of our voting securities are persons who were not nominated by our then current Board of Directors or an authorized committee thereof;
- our stockholders approve a merger or consolidation of our Company with another person, other than a merger or consolidation in which the holders of our voting securities outstanding immediately before such merger or consolidation continue to hold voting securities in the surviving or resulting corporation (in the same relative proportions to each other as existed before such event) comprising 80% or more of the voting power for all purposes of the surviving or resulting corporation; or
- our stockholders approve a transfer of substantially all of our assets to another person other than a transfer to a transferee, 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. If Mr. Bupp is terminated without cause, his benefits will continue for the longer of 36 months or the full term of the agreement.

#### Compensation of Other Named Executives

Our Executive Officers are employed under employment agreements of varying terms as outlined below. In addition, the CNG Committee will, on an annual basis, review the performance of our Company and may pay bonuses to our executives as it deems appropriate, in its discretion. Such review and bonus will be consistent with any bonus plan adopted by the CNG Committee that covers Mr. Bupp as well as the executive officers of the Company generally.

#### Anthony K. Blair

Employment Agreement. Anthony Blair is employed under a 24-month employment agreement effective January 1, 2009. The employment agreement provides for an annual base salary of \$157,000.

The CNG Committee will, on an annual basis, review the performance of our Company and of Mr. Blair and may pay a bonus to Mr. Blair as it deems appropriate, in its discretion. Such review and bonus will be consistent with any bonus plan adopted by the CNG Committee that covers the executive officers of the Company generally.

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

- by the Company without cause (cause is defined as any willful breach of a material duty by Mr. Blair in the course of his employment or willful and continued neglect of his duty as an employee);
  - by the expiration of the term of Mr. Blair's employment agreement; or
- by the resignation of Mr. Blair because his title, authority, responsibilities, salary, bonus opportunities or benefits have materially diminished, a material adverse change in his working conditions has occurred, his services are no longer required in light of the Company's business plan, or we breach the agreement;

then, Mr. Blair will be paid a severance payment of \$310,000 and will continue his benefits for the longer of 12 months or the remaining term of his employment agreement.

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

- the acquisition, directly or indirectly, by a person (other than our Company, an employee benefit plan established by the Board of Directors, or a participant in a transaction approved by the Board of Directors for the principal purpose of raising additional capital) of beneficial ownership of 30% or more of our securities with voting power in the next meeting of holders of voting securities to elect the directors;
- a majority of the directors elected at any meeting of the holders of our voting securities are persons who were not nominated by our then current Board of Directors or an authorized committee thereof;
- our stockholders approve a merger or consolidation of our Company with another person, other than a merger or consolidation in which the holders of our voting securities outstanding immediately before such merger or consolidation continue to hold voting securities in the surviving or resulting corporation (in the same relative proportions to each other as existed before such event) comprising 80% or more of the voting power for all purposes

of the surviving or resulting corporation; or

- our stockholders approve a transfer of substantially all of the assets of our Company to another person other than a transfer to a transferee, 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. Blair will be paid a severance amount of \$157,000 if his employment is terminated at the end of his employment agreement or without cause. If Mr. Blair is terminated without cause, his benefits will continue for the longer of 12 months or the full term of the agreement.

Brent L. Larson

Employment Agreement. Brent Larson is employed under a 24-month employment agreement effective January 1, 2009. The employment agreement provides for an annual base salary of \$184,000.

The terms of Mr. Larson's employment agreement are substantially identical to Mr. Blair's employment agreement, except that:

- If a change in control occurs with respect to our Company and the employment of Mr. Larson is concurrently or subsequently terminated, then Mr. Larson will be paid a severance payment of \$360,000; and
- Mr. Larson will be paid a severance amount of \$184,000 if his employment is terminated at the end of his employment agreement or without cause.

The CNG Committee will, on an annual basis, review the performance of our Company and of Mr. Larson and may pay a bonus to Mr. Larson as it deems appropriate, in its discretion. Such review and bonus will be consistent with any bonus plan adopted by the CNG Committee that covers the executive officers of the Company generally.



## Outstanding Equity Awards at Fiscal Year End

The following table presents certain information concerning outstanding equity awards held by the Named Executives as of December 31, 2008.

Name	Option Awards					Stock Awards		Note
	Number of Securities Underlying Options (#)	Unexercised Options (#)	Option Exercise Price	Option Expiration Date	Note	Number of Unearned Shares	Market Value of Unearned Shares (o)	
Anthony K. Blair	50,000	-	\$ 0.60	7/1/2014	(h)	50,000	\$ 28,500	(p)
	40,000	-	\$ 0.39	12/10/2014	(j)			
	30,000	-	\$ 0.26	12/27/2015	(k)			
	20,000	10,000	\$ 0.27	12/15/2016	(l)			
	6,667	13,333	\$ 0.35	7/27/2017	(m)			
	-	50,000	\$ 0.362	1/3/2018	(n)			
David C. Bupp	180,000	-	\$ 0.50	1/4/2010	(b)	300,000	\$ 171,000	(p)
	180,000	-	\$ 0.41	1/3/2011	(c)			
	180,000	-	\$ 0.42	1/7/2012	(d)			
	100,000	-	\$ 0.14	1/15/2013	(e)			
	70,000	-	\$ 0.13	2/15/2013	(f)			
	150,000	-	\$ 0.30	1/7/2014	(g)			
	150,000	-	\$ 0.49	7/28/2014	(i)			
	200,000	-	\$ 0.39	12/10/2014	(j)			
	200,000	-	\$ 0.26	12/27/2015	(k)			
	200,000	100,000	\$ 0.27	12/15/2016	(l)			
	-	200,000	\$ 0.362	1/3/2018	(n)			
Brent L. Larson	25,000	-	\$ 1.25	2/11/2009	(a)	50,000	\$ 28,500	(p)
	60,000	-	\$ 0.50	1/4/2010	(b)			
	60,000	-	\$ 0.41	1/3/2011	(c)			
	50,000	-	\$ 0.42	1/7/2012	(d)			
	40,000	-	\$ 0.14	1/15/2013	(e)			
	30,000	-	\$ 0.13	2/15/2013	(f)			
	70,000	-	\$ 0.30	1/7/2014	(g)			
	50,000	-	\$ 0.49	7/28/2014	(i)			
	50,000	-	\$ 0.39	12/10/2014	(j)			
	40,000	-	\$ 0.26	12/27/2015	(k)			
	33,333	16,667	\$ 0.27	12/15/2016	(l)			
	-	50,000	\$ 0.362	1/3/2018	(n)			

(a) Options were granted 2/11/1999 and vested as to one-third immediately and on each of the first two anniversaries of the date of grant.

(b)

- Options were granted 1/4/2000 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (c) Options were granted 1/3/2001 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (d) Options were granted 1/7/2002 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (e) Options were granted 1/15/2003 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (f) Options were granted 2/15/2003 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (g) Options were granted 1/7/2004 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (h) Options were granted 7/1/2004 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (i) Options were granted 7/28/2004 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (j) Options were granted 12/10/2004 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (k) Options were granted 12/27/2005 and vested as to one-third immediately and on each of the first two anniversaries of the date of grant.
- (l) Options were granted 12/15/2006 and vest as to one-third on each of the first three anniversaries of the date of grant.
- (m) Options were granted 7/27/2007 and vest as to one-third on each of the first three anniversaries of the date of grant.
- (n) Options were granted 1/3/2008 and vest as to one-third on each of the first three anniversaries of the date of grant.
- (o) Estimated by reference to the closing market price of the Company's common stock on December 31, 2008, pursuant to Instruction 3 to Item 402(p)(2) of Regulation S-K. The closing price of the Company's common stock on December 31, 2008, was \$0.57.
- (p) Restricted shares granted January 3, 2008. Pursuant to the terms of Restricted Stock Agreements between the Company and each grantee, the restricted shares will vest upon the approval by the United States Food and Drug Administration of the New Drug Application for Lymphoseek. If the employment of a grantee with the Company is terminated before all of the restricted shares have vested, then pursuant to the terms of the Restricted Stock Agreements all restricted shares that have not vested at the effective date of such grantee's termination shall immediately be forfeited by the grantee. Pursuant to its authority under Section 3.2 of the Restricted Stock Agreements the Company's Compensation, Nominating and Governance Committee eliminated the forfeiture provision in Section 3.2(b) of the Restricted Stock Agreements effective January 1, 2009, which provision effected the forfeiture of the shares if the vesting event did not occur before June 30, 2010.

## Compensation of Non-Employee Directors

Each non-employee director received an annual cash retainer of \$20,000 and earned an additional \$1,500 per board meeting attended in person or \$500 per telephonic board meeting during the fiscal year ended December 31, 2008. The Chairmen of the Company's Board of Directors and Audit Committee each received an additional annual retainer of \$10,000 for their services in those capacities during 2008. Members of committees of the Company's Board of Directors earned an additional \$500 per committee meeting attended in person or telephonically. We also reimbursed non-employee directors for travel expenses for meetings attended during 2008.

Each non-employee director also received 10,000 options to purchase common stock as a part of the Company's annual stock incentive grants, in accordance with the provisions of the Neoprobe Corporation Second Amended and Restated 2002 Stock Incentive Plan. The options granted to purchase common stock vested on the first anniversary of the date of grant and have an exercise price of \$0.362, the closing price of the Company's common stock as reported on the OTC Bulletin Board regulated quotation service on January 3, 2008, the date of grant. The aggregate number of option awards outstanding at March 15, 2009 for each Director is set forth in the footnotes to the beneficial ownership table provided in Part III, Item 12 of this Form 10-K. Directors who are also officers or employees of Neoprobe do not receive any compensation for their services as directors.

The following table sets forth certain information concerning the compensation of non-employee Directors for the fiscal year ended December 31, 2008.

Name	(a) Fees Earned or Paid in Cash	(b),(c) Option Awards	Total Compensation
Carl J. Aschinger, Jr.	\$ 37,500	\$ 3,046	\$ 40,546
Reuven Avital	28,000	3,046	31,046
Kirby I. Bland, M.D.	27,500	3,046	30,546
Owen E. Johnson, M.D.	27,500	6,011	33,511
Fred B. Miller	38,000	3,046	41,046
Gordon A. Troup	13,000	2,020	15,202
J. Frank Whitley, Jr.	28,000	3,046	31,046

(a) Amount represents fees earned during the fiscal year ended December 31, 2008 (i.e., the year to which the service relates). Quarterly retainers and meeting attendance fees are paid during the quarter following the quarter in which they are earned.

(b) Amount represents the dollar amount recognized for financial statement reporting purposes in accordance with SFAS No. 123(R). Assumptions made in the valuation of stock option awards are disclosed in Note 1(o) of the Notes to the Consolidated Financial Statements in this Form 10-K.

(c) At December 31, 2008, the non-employee directors held an aggregate of 1,057,500 options to purchase shares of common stock of the Company.

## Item 12. 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, 2008, 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.

	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders	5,619,500	\$ 0.40	2,370,500
Equity compensation plans not approved by security holders	-	-	-
<b>Total</b>	<b>5,619,500</b>	<b>\$ 0.40</b>	<b>2,370,500</b>

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

The following table sets forth, as of March 15, 2009, 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% 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.

Beneficial Owner	Number of Shares Beneficially Owned (*)	Percent of Class (**)
Carl J. Aschinger, Jr.	292,145(a)	(n)
Reuven Avital	404,256(b)	(n)
Anthony K. Blair	247,097(c)	(n)
Kirby I. Bland, M.D.	195,000(d)	(n)
David C. Bupp	6,920,309(e)	8.9%
Frederick O. Cope, Ph.D.	-(f)	(n)
Owen E. Johnson, M.D.	50,000(g)	(n)
Brent L. Larson	687,414(h)	1.0%
Fred B. Miller	376,000(i)	(n)
Gordon A. Troup	15,000(j)	(n)
J. Frank Whitley, Jr.	281,500(k)	(n)
All directors and officers as a group (13 persons)	10,011,377(l)(o)	12.5%
Platinum Montaur Life Sciences, LLC	3,758,650(m)	4.99%

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

(\*\*) Percent of class is calculated on the basis of the number of shares outstanding on March 15, 2009, plus the number of shares the person has the right to acquire within 60 days of March 15, 2009.

(a) This amount includes 140,000 shares issuable upon exercise of options which are exercisable within 60 days and 1,145 shares held in a trust account for which Mr. Aschinger is the custodian, but does not include 10,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(b) This amount consists of 139,256 shares of our common stock owned by Mittai Investments Ltd. (Mittai), an investment fund under the management and control of Mr. Avital, and 185,000 shares issuable upon exercise of options which are exercisable within 60 days but does not include 10,000 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 includes 163,334 shares issuable upon exercise of options which are exercisable within 60 days and 33,763 shares in Mr. Blair’s account in the 401(k) Plan, but it does not include 50,000 shares of unvested restricted

stock and 81,166 shares issuable upon exercise of options which are not exercisable within 60 days.

- (d) This amount includes 170,000 shares issuable upon exercise of options which are exercisable within 60 days but does not include 10,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (e) This amount includes 1,676,667 shares issuable upon exercise of options which are exercisable within 60 days, 770,000 warrants which are exercisable within 60 days, a promissory note convertible into 3,225,806 shares of our common stock, 203,746 shares that are held by Mr. Bupp's wife for which he disclaims beneficial ownership and 119,390 shares in Mr. Bupp's account in the 401(k) Plan, but it does not include 700,000 shares of unvested restricted stock and 233,333 shares issuable upon exercise of options which are not exercisable within 60 days.
- (f) This amount does not include 100,000 shares of unvested restricted stock and 50,000 shares issuable upon exercise of options which are not exercisable within 60 days.

- (g) This amount includes 30,000 shares issuable upon exercise of options which are exercisable within 60 days but does not include 10,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (h) This amount includes 500,000 shares issuable upon exercise of options which are exercisable within 60 days and 87,414 shares in Mr. Larson's account in the 401(k) Plan, but it does not include 50,000 shares of unvested restricted stock and 75,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (i) This amount includes 245,000 shares issuable upon exercise of options which are exercisable within 60 days and 81,000 shares held by Mr. Miller's wife for which he disclaims beneficial ownership, but does not include 10,000 shares issuable upon the exercise of options which are not exercisable within 60 days.
- (j) This amount does not include 20,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (k) This amount includes 260,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 10,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (l) This amount includes 3,900,000 shares issuable upon exercise of options which are exercisable within 60 days, 770,000 warrants which are exercisable within 60 days, a promissory note convertible into 3,225,806 shares of our common stock, 285,891 shares that are held by spouses of our Directors and Officers or in trusts for which they are custodian but for which they disclaim beneficial ownership and 253,224 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 920,000 shares of unvested restricted stock and 595,000 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 575,350 shares of common stock.
- (m) Platinum-Montaur Life Sciences, LLC (Montaur), 152 W. 57th Street, 54th Floor, New York, NY 10019, holds promissory notes in the principal amount of \$10,000,000 convertible into 21,794,871 shares of our common stock, warrants to purchase 20,333,333 shares of our common stock, and 3,000 shares of Series A 8% Cumulative Convertible Preferred Stock convertible into 6,000,000 shares of our common stock. Each of our convertible promissory notes held by Montaur, the warrants held by Montaur, and the Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series A 8% Cumulative Convertible Preferred Stock provide that those instruments are not convertible or exercisable if, after such conversion or exercise, Montaur would beneficially own more than 4.99% of our outstanding common stock. This provision may be waived by Montaur giving us at least 61 days prior written notice. Similarly, each of our convertible promissory notes and warrants held by Montaur provides that those instruments are not convertible or exercisable if, after such conversion or exercise, Montaur would beneficially own more than 9.99% of our outstanding common stock, subject to Montaur's right to request a waiver of this restriction in writing at least 61 days prior to the effective date of that waiver.
- (n) Less than one percent.
- (o) The address of all directors and executive offices is c/o Neoprobe Corporation, 425 Metro Place North, Suite 300, Dublin, Ohio 43017-1367.

### Item 13. Certain Relationships and Related Transactions, and Director Independence

#### Director Independence

Our Board of Directors has adopted the definition of "independence" as described under the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley) Section 301, Rule 10A-3 under the Securities Exchange Act of 1934 (the Exchange Act) and Nasdaq Rules 4200 and 4350. Our Board of Directors has determined that Messrs. Aschinger, Avital, Miller, Troup and Whitley, and Drs. Bland and Johnson meet the independence requirements.

See Liquidity and Capital Resources in Part II, Item 7 of this Form 10-K for information about our related party transactions.

Item 14. Principal Accountant Fees and Services

**Audit Fees.** The aggregate fees billed and expected to be billed for professional services rendered by BDO Seidman, LLP for the audit of the Company's annual consolidated financial statements for the 2008 fiscal year, the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2008 fiscal year, and consents related to the Company's registration statements filed during the 2008 fiscal year were \$177,540 (including direct engagement expenses). The aggregate fees billed for professional services rendered by BDO Seidman, LLP for the audit of the Company's annual consolidated financial statements for the 2007 fiscal year, the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-QSB for the 2007 fiscal year, and consents related to the Company's registration statements filed during the 2007 fiscal year were \$158,259 (including direct engagement expenses).



**Audit-Related Fees.** The aggregate fees billed by BDO Seidman, LLP for audit-related services for the 2007 fiscal year were \$2,385. No fees were billed by BDO Seidman, LLP for audit-related services for the 2008 fiscal year.

**Tax Fees.** The aggregate fees billed by BDO Seidman, LLP for tax-related services for the 2007 fiscal year were \$500. No fees were billed by BDO Seidman, LLP for tax-related services for the 2008 fiscal year.

**All Other Fees.** No fees were billed by BDO Seidman, LLP for services other than the audit, audit-related and tax services for the 2008 or 2007 fiscal years.

**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.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Neoprobe Corporation as corrected February 18, 1994 and amended June 27, 1994, June 3, 1996, March 17, 1999, May 9, 2000, June 13, 2003, July 27, 2004, June 22, 2005 and November 20, 2006 (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form SB-2 filed December 7, 2006).
3.2	Amended and Restated By-Laws dated July 21, 1993, as amended July 18, 1995, May 30, 1996 and July 26, 2007 (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K dated August 3, 2007, and incorporated herein by reference).
4.1	Neoprobe Corporation Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series A 8% Cumulative Convertible Preferred Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed January 2, 2008).
5.1	Opinion of Porter, Wright, Morris & Arthur LLP.*
10.1	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).
10.2	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).
10.3	Neoprobe Corporation Second Amended and Restated 2002 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 27, 2008).
10.4	Form of Stock Option Agreement under the Neoprobe Corporation Amended and Restated 2002 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 21, 2006).
10.5	Form of Restricted Stock Award and Agreement under the Neoprobe Corporation Amended and Restated 2002 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed January 9, 2008).
10.6	Form of Employment Agreement between the Company and certain named executive officers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 23, 2008). This Agreement is one of three substantially identical employment agreements and is accompanied by a schedule which identifies material details in which each agreement differs from the form filed herewith.
10.7	Schedule identifying material differences between the employment agreements incorporated by reference as Exhibit 10.6 to this Registration Statement on Form S-1 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 23, 2008).



- 10.8 Employment Agreement, commencing February 15, 2009, by and between the Company and Frederick O. Cope, Ph.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 17, 2009).
- 10.9 Technology Transfer Agreement dated July 29, 1992 between the Company and The Dow Chemical Corporation (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.10 to the Company's Form S-1 filed October 15, 1992).
- 10.10 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).
- 10.11 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).
- 10.12 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).
- 10.13 License Agreement dated January 30, 2002 between the Company and the Regents of the University of California, San Diego, as amended on May 27, 2003 and February 1, 2006 (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 10.11 to the Company's Annual Report on Form 10-KSB filed March 31, 2006).
- 10.14 Evaluation License Agreement dated March 31, 2005 between the Company and the Regents of the University of California, San Diego (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 10.12 to the Company's Annual Report on Form 10-KSB filed March 31, 2006).
- 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 10.13 to the Company's Annual Report on Form 10-KSB filed March 16, 2007).
- 10.16 First Amendment to Distribution Agreement, dated December 14, 2007, by and between the Company and Ethicon Endo-Surgery, Inc. (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 10.1 to the Company's Current Report on Form 8-K filed December 20, 2007).
- 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) (incorporated by reference to Exhibit 10.17 to the Company's December 31, 2004 Form 10-KSB).
- 10.18

Supply and Distribution Agreement, dated November 15, 2007, by and between the Company and Cardinal Health 414, LLC (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 10.1 to the Company's Current Report on Form 8-K filed November 21, 2007).

- 10.19 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).
- 10.20 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).
- 10.21 Stock Purchase Agreement dated October 22, 2003 between the Company and Bridges & Pipes, LLC. This agreement is one of 21 substantially identical agreements and is accompanied by a schedule identifying the other agreements omitted and setting forth the material details in which such documents differ from the one that is filed herewith (incorporated by reference to Exhibit 10.32 to the Company's registration statement on Form SB-2 filed December 2, 2003).
- 10.22 Registration Rights Agreement dated October 22, 2003 between the Company and Bridges & Pipes, LLC. This agreement is one of 21 substantially identical agreements and is accompanied by a schedule identifying the other agreements omitted and setting forth the material details in which such documents differ from the one that is filed herewith (incorporated by reference to Exhibit 10.33 to the Company's registration statement on Form SB-2 filed December 2, 2003).
- 10.23 Series R Warrant Agreement dated October 22, 2003 between the Company and Bridges & Pipes, LLC. This agreement is one of 21 substantially identical agreements and is accompanied by a schedule identifying the other agreements omitted and setting forth the material details in which such documents differ from the one that is filed herewith (incorporated by reference to Exhibit 10.34 to the Company's registration statement on Form SB-2 filed December 2, 2003).
- 10.24 Series S Warrant Agreement dated November 21, 2003 between the Company and Alberdale Capital, LLC. This agreement is one of 7 substantially identical agreements and is accompanied by a schedule identifying the other agreements omitted and setting forth the material details in which such documents differ from the one that is filed herewith (incorporated by reference to Exhibit 10.35 to the Company's registration statement on Form SB-2 filed December 2, 2003).
- 10.25 Common Stock Purchase Agreement between the Company and Fusion Capital Fund II, LLC dated December 1, 2006 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed December 4, 2006).
- 10.26 First Amendment to Common Stock Purchase Agreement between the Company and Fusion Capital Fund II, LLC, dated December 24, 2008 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 31, 2008).
- 10.27 Registration Rights Agreement dated December 1, 2006, between the Company and Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed December 4, 2006).
- 10.28 10% Convertible Note Purchase Agreement, dated July 3, 2007, between the Company and David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 9, 2007).

- 10.29 Amendment to Convertible Note Purchase Agreement, dated December 26, 2007, between the Company and David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed January 2, 2008).

- 10.30 Neoprobe Corporation 10% Convertible Promissory Note Due July 8, 2007, executed in favor of David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 9, 2007).
- 10.31 Amended Neoprobe Corporation 10% Convertible Promissory Note Due December 31, 2011, executed in favor of David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 10.32 Security Agreement, dated December 26, 2007, by and between the Company and David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 10.33 Series V Warrant to Purchase Common Stock of Neoprobe Corporation issued to David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed July 9, 2007).
- 10.34 Additional Series V Warrant to Purchase Common Stock of Neoprobe Corporation issued to David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.13 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 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 (incorporated by reference to Exhibit 10.35 to the Company's December 31, 2004 Form 10-KSB. This is the form of six substantially identical agreements. A schedule identifying the warrants and setting forth the material details in which such agreements differ from the form that is incorporated by reference herein is filed as Exhibit 10.34 to this Annual Report on Form 10-K).
- 10.36 Registration Rights Agreement, dated July 3, 2007, by and among Neoprobe Corporation and David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed July 9, 2007).
- 10.37 Securities Purchase Agreement, dated as of December 26, 2007, by and between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 10.38 Amendment and Waiver for Securities Purchase Agreement, dated April 16, 2008, between Neoprobe Corporation and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 18, 2008).
- 10.39 Neoprobe Corporation 10% Series A Convertible Senior Secured Promissory Note in the principal amount of \$7,000,000, due December 26, 2011 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 10.40 Second Amendment to 10% Series A Senior Secured Convertible Promissory Note, dated April 16, 2008, between Neoprobe Corporation and Platinum-Montaur Life Sciences, LLC (incorporated by



reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed April 18, 2008).

- 10.41 Neoprobe Corporation 10% Series B Convertible Senior Secured Promissory Note in the principal amount of \$3,000,000, due December 26, 2011 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed April 18, 2008).
- 10.42 Series W Warrant to Purchase Shares of Common Stock of Neoprobe Corporation issued to Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 10.43 Series X Warrant to Purchase Shares of Common Stock of Neoprobe Corporation issued to Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed April 18, 2008).
- 10.44 Series Y Warrant to Purchase Shares of Common Stock of Neoprobe Corporation issued to Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 9, 2008).
- 10.45 Registration Rights Agreement, dated December 26, 2007, between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 10.46 Second Amendment to Registration Rights Agreement, dated April 16, 2008, between Neoprobe Corporation and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 18, 2008).
- 10.47 Third Amendment to Registration Rights Agreement, dated July 10, 2008, between Neoprobe Corporation and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.55 to pre-effective amendment No. 2 to the Company's Registration Statement on Form S-1, filed July 24, 2008, Registration file No. 333-150650).
- 10.48 Fourth Amendment to Registration Rights Agreement, dated December 5, 2008, between Neoprobe Corporation and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 9, 2008).
- 10.49 Security Agreement, dated December 26, 2007, between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 10.50 Patent, Trademark, and Copyright Security Agreement, dated December 25, 2007, by and among Neoprobe Corporation, Cardiosonix Ltd., Cira Biosciences, Inc. and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed January 2, 2008).
- 21.1 Subsidiaries of the registrant.\*
- 23.1 Consent of BDO Seidman, LLP.\*
- 24.1 Power 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.

SIGNATURES

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

Dated: March 30, 2009

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 30, 2009
/s/ Brent L. Larson* Brent L. Larson	Vice President, Finance and Chief Financial Officer (principal financial officer)	March 30, 2009
/s/ Carl J. Aschinger, Jr.* Carl J. Aschinger, Jr.	Chairman, Director	March 30, 2009
/s/ Reuven Avital* Reuven Avital	Director	March 30, 2009
/s/ Kirby I. Bland* Kirby I. Bland	Director	March 30, 2009
/s/ Owen E. Johnson* Owen E. Johnson	Director	March 30, 2009
/s/ Fred B. Miller* Fred B. Miller	Director	March 30, 2009
/s/ Gordon A. Troup* Gordon A. Troup	Director	March 30, 2009
/s/ J. Frank Whitley, Jr.* J. Frank Whitley, Jr.	Director	March 30, 2009

\*By: /s/ David C. Bupp  
David C. Bupp, Attorney-in-fact



SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

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NEOPROBE CORPORATION

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FORM 10-K ANNUAL REPORT  
FOR THE FISCAL YEARS ENDED:  
DECEMBER 31, 2008 AND 2007

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FINANCIAL STATEMENTS

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NEOPROBE CORPORATION and SUBSIDIARY

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Report of Independent Registered Public Accounting Firm

Board of Directors  
Neoprobe Corporation  
Dublin, Ohio

We have audited the accompanying consolidated balance sheets of Neoprobe Corporation as of December 31, 2008 and 2007 and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, 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 at December 31, 2008 and 2007 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO Seidman, LLP

Chicago, Illinois  
March 27, 2009

Neoprobe Corporation and Subsidiaries  
Consolidated Balance Sheets

December 31, 2008 and 2007

ASSETS	2008	2007
<b>Current assets:</b>		
Cash	\$ 3,565,837	\$ 1,540,220
Available-for-sale securities	495,383	-
Accounts receivable, net	1,644,070	1,621,910
Inventory	961,861	1,237,403
Prepaid expenses and other	573,573	247,035
<b>Total current assets</b>	<b>7,240,724</b>	<b>4,646,568</b>
Property and equipment	2,060,588	1,918,343
Less accumulated depreciation and amortization	1,669,796	1,630,740
	390,792	287,603
Patents and trademarks	3,020,001	3,016,783
Acquired technology	237,271	237,271
	3,257,272	3,254,054
Less accumulated amortization	1,863,787	1,652,912
	1,393,485	1,601,142
Other assets	594,449	527,634
<b>Total assets</b>	<b>\$ 9,619,450</b>	<b>\$ 7,062,947</b>

Continued

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Neoprobe Corporation and Subsidiaries  
Consolidated Balance Sheets, continued

LIABILITIES AND STOCKHOLDERS' DEFICIT	2008	2007
<b>Current liabilities:</b>		
Accounts payable	\$ 731,220	\$ 778,085
Accrued liabilities and other	917,676	801,949
Capital lease obligations	9,084	14,592
Deferred revenue	526,619	451,512
Notes payable to finance companies	137,857	124,770
<b>Total current liabilities</b>	<b>2,322,456</b>	<b>2,170,908</b>
Capital lease obligations	11,095	2,422
Deferred revenue	490,165	623,640
Note payable to CEO, net of discounts of \$76,294 and \$95,786, respectively	923,706	904,214
Notes payable to investors, net of discounts of \$5,001,149 and \$2,600,392, respectively	4,998,851	4,399,608
Derivative liabilities	853,831	2,853,476
Other liabilities	45,071	52,273
<b>Total liabilities</b>	<b>9,645,175</b>	<b>11,006,541</b>
<b>Commitments and contingencies</b>		
Preferred stock; \$.001 par value; 5,000,000 shares authorized; 3,000 Series A shares, par value \$1,000, issued and outstanding at December 31, 2008; none outstanding at December 31, 2007	3,000,000	-
<b>Stockholders' deficit:</b>		
Common stock; \$.001 par value; 150,000,000 shares authorized; 70,862,641 and 67,240,030 shares issued and outstanding at December 31, 2008 and 2007, respectively	70,863	67,240
Additional paid-in capital	145,742,044	136,765,697
Accumulated deficit	(148,840,015)	(140,776,531)
Unrealized gain on available-for-sale securities	1,383	-
<b>Total stockholders' deficit</b>	<b>(3,025,725)</b>	<b>(3,943,594)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 9,619,450</b>	<b>\$ 7,062,947</b>

See accompanying notes to consolidated financial statements.

Neoprobe Corporation and Subsidiaries  
Consolidated Statements of Operations

	Years Ended December 31,	
	2008	2007
<b>Revenues:</b>		
Net sales	\$ 7,714,520	\$ 7,124,811
License and other revenue	171,750	-
Total revenues	7,886,270	7,124,811
<b>Cost of goods sold</b>		
	3,010,232	3,184,706
Gross profit	4,876,038	3,940,105
<b>Operating expenses:</b>		
Research and development	4,505,622	2,865,539
Selling, general and administrative	3,412,534	2,837,344
Total operating expenses	7,918,156	5,702,883
Loss from operations	(3,042,118)	(1,762,778)
<b>Other income (expense):</b>		
Interest income	60,860	70,976
Interest expense	(1,744,825)	(2,284,135)
Loss on extinguishment of debt	-	(859,955)
Change in derivative liabilities	(451,381)	(247,876)
Other	11,238	(4,444)
Total other expenses, net	(2,124,108)	(3,325,434)
Net loss	\$ (5,166,226)	\$ (5,088,212)
<b>Net loss per common share:</b>		
Basic	\$ (0.08)	\$ (0.08)
Diluted	\$ (0.08)	\$ (0.08)
<b>Weighted average shares outstanding:</b>		
Basic	68,594,172	62,921,491
Diluted	68,594,172	62,921,491

See accompanying notes to consolidated financial statements.

Neoprobe Corporation and Subsidiaries  
Consolidated Statements of Stockholders' Deficit

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance, December 31, 2006	59,624,379	\$ 59,624	\$ 135,330,668	\$ (135,688,319)	\$ -	\$ (298,027)
Cancelled restricted stock that did not vest	(130,000)	(130)	-	-	-	(130)
Issued stock to 401(k) plan at \$0.28	107,313	108	29,423	-	-	29,531
Issued stock in connection with stock purchase agreement, net of costs	7,588,338	7,588	1,703,953	-	-	1,711,541
Issued stock as fees to an investment banking firm	50,000	50	11,950	-	-	12,000
Effect of beneficial conversion feature of convertible promissory note	-	-	86,587	-	-	86,587
Issued warrants to purchase common stock	-	-	175,719	-	-	175,719
Repurchased warrants related to extinguishment of debt	-	-	(675,000)	-	-	(675,000)
Stock compensation expense	-	-	102,397	-	-	102,397
Net loss	-	-	-	(5,088,212)	-	(5,088,212)
Balance, December 31, 2007	67,240,030	67,240	136,765,697	(140,776,531)	-	(3,943,594)
Issued restricted stock to employees	480,000	480	(30)	-	-	450
Issued stock to investor advisory service firms	117,500	118	78,433	-	-	78,551
Issued stock to 401(k) plan at \$0.26	114,921	115	29,916	-	-	30,031
Issued stock upon exercise of warrants	2,365,190	2,365	167,441	-	-	169,806
Issued stock upon exercise of options	185,000	185	61,715	-	-	61,900
	360,000	360	215,640	-	-	216,000

Issued stock as a commitment fee in connection with a stock purchase agreement							
Paid preferred stock issuance costs	-	-	(180,000)	-	-	(180,000)	
Paid common stock issuance costs	-	-	(900)	-	-	(900)	
Issued warrants to purchase common stock	-	-	2,473,087	(1,130,629)	-	1,342,458	
Effect of beneficial conversion feature of convertible promissory note	-	-	1,443,845	-	-	1,443,845	
Effect of beneficial conversion feature of convertible preferred stock	-	-	1,550,629	(1,550,629)	-	-	
Effect of put option feature of convertible preferred stock	-	-	-	(216,000)	-	(216,000)	
Reclassified derivative liabilities	-	-	2,924,994	-	-	2,924,994	
Stock compensation expense	-	-	211,577	-	-	211,577	
Comprehensive income (loss):							
Net loss	-	-	-	(5,166,226)	-	(5,166,226)	
Unrealized gain on available-for-sale securities	-	-	-	-	1,383	1,383	
Total comprehensive loss	-	-	-	-	-	(5,164,843)	
Balance, December 31, 2008	70,862,641	70,863	\$ 145,742,044	\$ (148,840,015)	\$ 1,383	\$ (3,025,725)	

See accompanying notes to consolidated financial statements.

Neoprobe Corporation and Subsidiaries  
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (5,166,226)	\$ (5,088,212)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	183,209	171,713
Amortization of intangible assets	225,143	233,006
Loss on disposal and abandonment of assets	30,850	22,551
Amortization of debt discount and debt offering costs	706,064	1,406,195
Provision for bad debts	849	1,000
Stock compensation expense	211,577	102,397
Loss on extinguishment of debt	-	859,955
Change in derivative liabilities	451,381	247,876
Other	130,341	29,400
Change in operating assets and liabilities:		
Accounts receivable	(23,009)	(376,821)
Inventory	93,372	(166,838)
Prepaid expenses and other assets	131,039	177,351
Accounts payable	(46,865)	109,797
Accrued liabilities and other liabilities	108,525	319,337
Deferred revenue	(58,368)	686,089
Net cash used in operating activities	(3,022,118)	(1,265,204)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(690,000)	-
Maturities of available-for-sale securities	196,000	-
Purchases of property and equipment	(116,352)	(41,274)
Proceeds from sales of property and equipment	495	-
Patent and trademark costs	(17,486)	(6,736)
Net cash used in investing activities	(627,343)	(48,010)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock	3,000,000	-
Payment of preferred stock offering costs	(180,000)	-
Proceeds from issuance of common stock	232,156	1,900,000
Payment of common stock offering costs	(900)	(22,674)
Proceeds from notes payable	3,000,000	8,000,000
Payment of debt issuance costs	(200,154)	(565,004)
Payment of notes payable	(158,304)	(8,271,702)
Payments under capital leases	(17,720)	(14,841)
Payment for repurchase of warrants	-	(675,000)
Net cash provided by financing activities	5,675,078	350,779

Net increase (decrease) in cash	2,025,617	(962,435)
Cash, beginning of year	1,540,220	2,502,655
Cash, end of year	\$ 3,565,837	\$ 1,540,220

See accompanying notes to consolidated financial statements.

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Notes to the Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies:

a. **Organization and Nature of Operations:** Neoprobe Corporation (Neoprobe, 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 medical devices: the first is a line of gamma radiation detection equipment used in the application of sentinel lymph node biopsy (SLNB), 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 & Johnson company. For the years ended December 31, 2008 and 2007, 93% and 91% of net sales, respectively, were made to EES. The loss of this customer would have a significant adverse effect on our operating results. In addition, we operate a blood flow measurement device business that was initiated as a result of our acquisition of Cardiosonix Ltd. (Cardiosonix, formerly Biosonix Ltd.) on December 31, 2001.

We also have developmental and/or intellectual property rights related to two drugs that could be used in connection with gamma detection devices in cancer surgeries. The first, Lymphoseek®, is intended to be used in determining the spread of certain solid tumor cancers into the lymphatic system. The second, RIGScan® CR, is intended to be used to help surgeons locate cancerous or disease involved tissue during colorectal cancer surgeries. 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.

In addition, 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 is combining our activated cellular therapy (ACT) technology for patient-specific oncology treatment with similar technology licensed from Cira LLC, a privately held company, for treating viral and autoimmune diseases. Neoprobe owns approximately 90% of the outstanding shares of Cira Bio with the remaining shares being held by the principals of Cira LLC. During the third quarter of 2007, we executed an option agreement with Cira Ltd., the sole minority shareholder in Cira Bio, whereby Neoprobe may acquire Cira Ltd.'s 10% interest in Cira Bio for \$250,000. The option to acquire Cira Ltd.'s interest in Cira Bio expired on June 30, 2008.

b. **Principles of Consolidation:** Our consolidated financial statements include the accounts of Neoprobe, our wholly-owned subsidiary, Cardiosonix, and our majority-owned subsidiary, Cira Bio. All significant inter-company accounts were eliminated in consolidation.

c. **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.

d. **Financial Instruments and Fair Value:** We adopted Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements, for financial assets and liabilities as of January 1, 2008. SFAS No. 157 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair

value hierarchy under SFAS No. 157 are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

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Notes to the Consolidated Financial Statements

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. In determining the appropriate levels, we perform a detailed analysis of the assets and liabilities that are subject to SFAS No. 157. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3. In estimating the fair value of our derivative liabilities, we used the Black-Scholes option pricing model and, where necessary, other macroeconomic, industry and Company-specific conditions. See Note 2.

The following methods and assumptions were used to estimate the fair value of each class of financial instruments:

- (1) Cash, accounts receivable, accounts payable, and accrued liabilities: The carrying amounts approximate fair value because of the short maturity of these instruments.
- (2) Available-for-sale securities: Available-for-sale securities are recorded at fair value. Unrealized holding gains and losses on available-for-sale securities are excluded from earnings and are reported as a separate component of other comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities are determined on a specific identification basis.

A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary results in a reduction in carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related available-for-sale security as an adjustment to yield using the effective interest method. Dividend and interest income are recognized when earned.

Available-for-sale securities are accounted for on a specific identification basis. As of December 31, 2008, we held available-for-sale securities with an aggregate fair value of \$495,383, including \$1,383 of net unrealized gains recorded in accumulated other comprehensive income. As of December 31, 2008, all of our available-for-sale securities were invested in short-term certificates of deposit with maturity dates within 1 year. Available-for-sale securities were classified as current based on their maturity dates as well as our intent to use them to fund short-term working capital needs. We held no available-for-sale securities at December 31, 2007.

- (3) 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, 2008 and 2007, the carrying values of these instruments approximate fair value.
- (4) Note payable to CEO: The carrying value of our debt is presented as the face amount of the note less the unamortized discount related to the initial estimated fair value of the warrants to purchase common stock issued in connection with the note. At December 31, 2008, the note payable to our CEO had an estimated fair value of \$1.8 million. At December 31, 2007, the carrying value of the note payable to our CEO approximated fair value.
- (5) Notes payable to outside investors: The carrying value of our debt is presented as the face amount of the notes less the unamortized discounts related to the fair value of the beneficial conversion feature, the initial estimated fair value of the put options embedded in the notes and the initial estimated fair value of the warrants to purchase

common stock issued in connection with the notes. At December 31, 2008, the notes payable to outside investors had an estimated fair value of \$15.9 million. At December 31, 2007, the carrying value of the notes payable to outside investors approximated fair value.

## Notes to the Consolidated Financial Statements

e. Cash and Cash Equivalents: There were no cash equivalents at December 31, 2008 or 2007. No cash was restricted as of December 31, 2008 or 2007.

f. 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. During 2008 and 2007, we wrote off \$30,000 and \$142,000, respectively, of excess and obsolete materials, primarily due to design changes to our Quantix® product line.

From time to time, we capitalize certain inventory costs associated with our Lymphoseek product prior to regulatory approval and product launch based on management's judgment of probable future commercial use and net realizable value of the inventory. We could be required to permanently write down previously capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the inventory previously written down becomes available and is used for commercial sale. During 2007, we capitalized \$150,000 associated with our Lymphoseek product. During 2008, we wrote off \$153,000 of previously capitalized Lymphoseek inventory due to changes in our projections of the probability of future commercial use for the specific units previously capitalized.

The components of net inventory at December 31, 2008 and 2007 are as follows:

	2008	2007
Materials and component parts	\$ 380,912	\$ 471,753
Work-in-process	-	151,741
Finished goods	580,949	613,909
	\$ 961,861	\$ 1,237,403

g. 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 \$44,000 and \$57,000 of equipment under capital leases with accumulated amortization of \$25,000 and \$47,000 at December 31, 2008 and 2007, respectively. During 2008 and 2007, we recorded losses of \$31,000 and \$21,000, respectively, on the disposal of property and equipment.

The major classes of property and equipment are as follows:

	Useful Life	2008	2007
Production machinery and equipment	5 years	\$ 736,840	\$ 720,225
Other machinery and equipment, primarily research equipment, loaners and computers	2 – 5 years	733,590	655,609
Furniture and fixtures	7 years	349,369	340,007
Software	3 years	166,107	127,820
Leasehold improvements	Life of Lease	74,682	74,682
		\$ 2,060,588	\$ 1,918,343

1 We amortize leasehold improvements over the life of the lease, which in all cases is shorter than the estimated useful life of the asset.

h. 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. Acquired technology costs are amortized using the straight-line method over the estimated useful life of seven years. 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.

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## Notes to the Consolidated Financial Statements

The major classes of intangible assets are as follows:

	Wtd Avg Life	December 31, 2008		December 31, 2007	
		Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents and trademarks	7.8 yrs	\$ 3,020,001	\$ 1,626,516	\$ 3,016,783	\$ 1,449,350
Acquired technology	0 yrs	237,271	237,271	237,271	203,562
<b>Total</b>		<b>\$ 3,257,272</b>	<b>\$ 1,863,787</b>	<b>\$ 3,254,054</b>	<b>\$ 1,652,912</b>

During 2008 and 2007, we recorded \$225,000 and \$233,000, respectively, of intangible asset amortization in general and administrative expenses. During 2007, we wrote off \$1,000 of intangible assets related to patents and trademarks that were determined to have no recoverable value. No intangible assets were written off during 2008.

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

	Estimated Amortization Expense
For the year ended 12/31/2009	\$ 170,957
For the year ended 12/31/2010	170,341
For the year ended 12/31/2011	169,224
For the year ended 12/31/2012	168,885
For the year ended 12/31/2013	168,675

i. Impairment or Disposal of Long-Lived Assets: We account for the impairment of long-lived assets in accordance with the provisions of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This Statement requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. We recorded no impairment charges during 2008 or 2007.

j. 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 2008 and 2007, we incurred \$200,000 and \$565,000, respectively, of debt issuance costs related to notes payable. During 2007, we expensed \$209,000 of deferred debt issuance costs related to debt refinancing activities. Other assets include deferred debt issuance costs of \$588,000 and \$496,000 at December 31, 2008 and 2007, respectively. See Note 7.

k. Deferred Revenue: Deferred revenue as of December 31, 2008 and 2007 consists primarily of \$500,000 in non-refundable license fees and reimbursement of past research and development expenses which EES paid us as consideration for extending our distribution agreement with them. We intend to recognize the \$500,000 payment as license revenue on a straight-line basis over the extended term of the agreement, or January 2009 through

December 2013. In addition, deferred revenue as of December 31, 2008 and 2007 includes 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.



Notes to the Consolidated Financial Statements

l. Derivatives: We account for derivatives in accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, which provides accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are required to be bifurcated from the debt instrument and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. See Note 7.

m. Revenue Recognition:

(1) Product Sales: We derive revenues primarily from sales of our medical devices. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a common carrier. We generally recognize sales revenue when the products are shipped and the earnings process has been completed. 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. Our customers generally 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 purchased demonstration units in the ordinary course of business nor do we have any performance obligations other than normal product warranty obligations. To the extent that the earnings process has not been completed, revenue is deferred. To the extent we enter into multiple-element arrangements, we allocate revenue based on the relative fair value of the elements.

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

(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 shipped back to the customer.

n. Research and Development Costs: All costs related to research and development are expensed as incurred.

o. Stock-Based Compensation: At December 31, 2008, 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 Second Amended and Restated 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 stock awards may be granted to our consultants and agents. Total shares authorized under each plan are 2 million shares, 1.5 million shares and 7 million shares,

respectively. Although options are still outstanding under the Amended Plan and the 1996 Plan, these plans are considered expired and no new grants may be made from them. 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 date of the grant.

## Notes to the Consolidated Financial Statements

Options granted under the Amended Plan, the 1996 Plan and the 2002 Plan generally vest on an annual basis over one to 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 the Company. The Company issues new shares of our common stock upon exercise of stock options.

Compensation cost arising from stock-based awards is recognized as expense using the straight-line method over the vesting period. As of December 31, 2008, there was approximately \$321,000 of total unrecognized compensation cost related to unvested stock-based awards, which we expect to recognize over remaining weighted average vesting terms of 0.8 years. For the years ended December 31, 2008 and 2007, our total stock-based compensation expense was approximately \$212,000 and \$102,000, respectively. We have not recorded any income tax benefit related to stock-based compensation for the years ended December 31, 2008 and 2007.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model to value share-based payments. Expected volatilities are based on the Company's historical volatility, which management believes represents the most accurate basis for estimating expected volatility under the current circumstances. Neoprobe uses historical data to estimate forfeiture rates. The expected term of options granted is based on the vesting period and the contractual life of the options. The risk-free rate is based on the U.S. Treasury yield in effect at the time of the grant. The assumptions used for the years ended December 31, 2008 and 2007 are noted in the following table:

	2008	2007
Expected volatility	93%-104%	102%-104%
Weighted-average volatility	101%	103%
Expected dividends	-	-
Expected term	5.9 years	5.8 years
Risk-free rate	3.4%	4.6%

A summary of stock option activity under our stock option plans as of December 31, 2008, and changes during the year then ended is presented below:

	Year Ended December 31, 2008			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	5,495,473	\$ 0.42		
Granted	576,000	\$ 0.42		
Exercised	(185,000)	\$ 0.33		
Forfeited	-	-		
Expired	(266,973)	\$ 1.02		
Outstanding at end of period	5,619,500	\$ 0.40	5.3 years	\$ 1,102,325
Exercisable at end of period	4,880,167	\$ 0.40	4.8 years	\$ 958,712

The weighted average grant-date fair value of options granted in 2008 and 2007 was \$0.33 and \$0.28, respectively. During 2008, 185,000 stock options with an aggregate intrinsic value of \$43,550 were exercised in

exchange for issuance of 185,000 shares of our common stock, resulting in proceeds of \$61,900.

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## Notes to the Consolidated Financial Statements

A summary of the status of our unvested restricted stock as of December 31, 2008, and changes during the year then ended is presented below:

	Year Ended December 31, 2008	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	-	-
Granted	480,000	\$ 0.38
Vested	(7,000)	\$ 0.65
Forfeited	-	-
Unvested at end of period	473,000	\$ 0.37

During 2008, 7,000 shares of restricted stock vested with an aggregate fair value of \$4,060. During 2007, all of our then-outstanding restricted shares were effectively cancelled due to failure to vest under the terms of issuance of these shares. Restricted shares generally vest upon occurrence of a specific event or achievement of goals as defined in the grant agreements. As a result, we have recorded compensation expense related to grants of restricted stock based on management's estimates of the probable dates of the vesting events. See Note 17(a).

p. **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. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2008 and 2007. See Note 8.

In July 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes—An Interpretation of FASB Statement No. 109 (FIN 48). We adopted the provisions of FIN 48 on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with FASB Statement No. 109. FIN 48 also prescribes a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. No adjustment was made to the beginning retained earnings balance as the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of December 31, 2008 or 2007. Should the Company need to accrue interest or penalties on uncertain tax positions, it would recognize the interest as interest expense and the penalties as a selling, general and administrative expense. As of December 31, 2008, federal and state tax returns for tax years 2005-2007 remained subject to examination by tax authorities.

q. **Recent Accounting Developments:** In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 applies

under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS No. 157 does not require any new fair value measurements. SFAS No. 157 was initially effective for Neoprobe beginning January 1, 2008. In February 2008, the FASB approved the issuance of FASB Staff Position (FSP) FAS 157-2. FSP FAS 157-2 allows entities to electively defer the effective date of SFAS No. 157 until January 1, 2009 for nonfinancial assets and nonfinancial liabilities except those items recognized or disclosed at fair value on at least an annual basis. We will apply the fair value measurement and disclosure provisions of SFAS No. 157 to nonfinancial assets and liabilities effective January 1, 2009. The application of such is not expected to be material to our consolidated results of operations or financial condition. See Note 1(d) and Note 2 for a discussion regarding the January 1, 2008 implementation of SFAS No. 157 relating to our financial assets and liabilities.

## Notes to the Consolidated Financial Statements

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities – Including an Amendment of FASB Statement No. 115 (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value at specified election dates. Most of the provisions of SFAS No. 159 apply only to entities that elect the fair value option. However, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. The fair value option established by SFAS No. 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The fair value option may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method, is irrevocable (unless a new election date occurs), and is applied only to entire instruments and not to portions of instruments. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We adopted SFAS No. 159 as required on January 1, 2008; however, we did not elect to measure any of our currently outstanding financial instruments using the fair value option outlined in SFAS No. 159. As such, the adoption of SFAS No. 159 did not have any impact on our consolidated results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations (SFAS No. 141(R)). SFAS No. 141(R) retains the fundamental requirements of the original pronouncement requiring that the acquisition method (formerly called the purchase method) of accounting be used for all business combinations and for an acquirer to be identified for each business combination. SFAS No. 141(R) defines the acquirer as the entity that obtains control of one or more businesses in the business combination, establishes the acquisition date as the date that the acquirer achieves control and requires the acquirer to recognize the assets and liabilities assumed and any noncontrolling interest at their fair values as of the acquisition date. SFAS No. 141(R) requires, among other things, that the acquisition-related costs be recognized separately from the acquisition. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and is required to be adopted by Neoprobe beginning January 1, 2009. The effect the adoption of SFAS No. 141(R) will have on us will depend on the nature and size of acquisitions we complete after we adopt SFAS No. 141(R), if any.

Also in December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements – an Amendment of ARB No. 51 (SFAS No. 160). SFAS No. 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of ARB No. 51's consolidation procedures for consistency with the requirements of SFAS No. 141(R), Business Combinations. SFAS No. 160 is effective for fiscal years and interim periods within those fiscal years beginning on or after December 15, 2008, and is required to be adopted by Neoprobe beginning January 1, 2009. Earlier adoption is prohibited. SFAS No. 160 shall be applied prospectively as of the beginning of the fiscal year in which it is adopted, except for the presentation and disclosure requirements. The presentation and disclosure requirements shall be applied retrospectively for all periods presented. We do not expect the adoption of SFAS No. 160 to have a material effect on our consolidated results of operations or financial condition.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force (EITF) on EITF Issue No. 07-1, Accounting for Collaborative Arrangements. EITF No. 07-1 focuses on defining a collaborative arrangement as well as the accounting for transactions between participants in a collaborative arrangement and between the participants in the arrangement and third parties. The EITF concluded that both types of transactions should be reported in each participant's respective income statement. EITF No. 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and should be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the

effective date. We do not expect EITF No. 07-1 to have a material effect on our consolidated results of operations or financial condition.

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## Notes to the Consolidated Financial Statements

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement No. 133 (SFAS No. 161). SFAS No. 161 amends and expands the disclosure requirements of Statement No. 133 to provide a better understanding of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for, and their effect on an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for fiscal years beginning after November 15, 2008. We are currently evaluating the impact that the adoption of SFAS No. 161 will have on our derivative disclosures.

In June 2008, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-5, Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock. EITF Issue No. 07-5 clarifies the determination of whether equity-linked instruments (or embedded features), such as our convertible notes or warrants to purchase our common stock, are considered indexed to our own stock, which would qualify as a scope exception under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. EITF Issue No. 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. We are currently evaluating the impact that the adoption of EITF Issue No. 07-5 will have on our consolidated financial statements. If we determine that the provisions of EITF Issue No. 07-5 are applicable to our financial instruments, we currently estimate that the adoption of EITF Issue No. 07-5 will result in a cumulative effect adjustment of approximately \$3.9 million that would be recorded as additional accumulated deficit during the first quarter of 2009 as well as the disclosure of additional derivative liabilities in our balance sheet in future reports.

2. Fair Value Hierarchy:

The following tables set forth by level financial assets and liabilities measured at fair value on a recurring basis.

Assets and Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2008

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)			Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2008		
<b>Assets:</b>								
Available-for-sale securities	\$	495,383	\$	-	\$	-	\$	495,383
<b>Liabilities:</b>								
Derivative liabilities related to conversion and put options	\$	-	\$	-	\$	853,831	\$	853,831

## Notes to the Consolidated Financial Statements

## Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2007

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2007
<b>Liabilities:</b>				
Derivative liabilities related to warrants	\$ -	\$ 1,254,404	\$ -	\$ 1,254,404
Derivative liabilities related to conversion and put options	-	-	1,599,072	1,599,072
Total derivative liabilities	\$ -	\$ 1,254,404	\$ 1,599,072	\$ 2,853,476

The following table sets forth a summary of changes in the fair value of our Level 3 liabilities for the year ended December 31, 2008:

Description	Balance at December 31, 2007	Unrealized Losses	Issuance of Put Options Related to the Montaur Notes and Preferred Stock	Transfers In and/or (Out) (See Note 7)	Balance at December 31, 2008
Derivative liabilities related to conversion and put options	\$ 1,599,072	\$ 180,727	\$ 473,968	\$ (1,399,936)	\$ 853,831

The Level 2 Series W warrant derivative liability and the Level 3 Series A Note conversion option derivative liability were \$1,254,404 and \$1,289,215 as of January 1, 2008, respectively. These derivative liabilities incurred unrealized losses of \$270,654 and \$110,721, respectively, through March 14, 2008 when the Series W warrant and Series A Note were amended as discussed in Note 7. As a result of the amendment, the Level 2 warrant derivative liability and the Level 3 conversion option derivative liability required equity treatment. The warrant derivative liability and the conversion option derivative liability were reclassified to equity on March 14, 2008 at their fair value amounts of \$1,525,058 and \$1,399,936, respectively, for a total of \$2,924,994.

The unrealized gains and losses on the derivatives are classified in other expenses as a change in derivative liabilities in the statement of operations. Fair value of available-for-sale securities is determined based on a discounted cash flow analysis using current market rates. Fair value of conversion and put option liabilities is determined based on a probability-weighted Black-Scholes option pricing model calculation.

## Notes to the Consolidated Financial Statements

## 3. Earnings Per Share:

Basic earnings (loss) per share is 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 unvested restricted stock, convertible securities, options and warrants, if dilutive.

	Year Ended December 31, 2008		Year Ended December 31, 2007	
	Basic Earnings Per Share	Diluted Earnings Per Share	Basic Earnings Per Share	Diluted Earnings Per Share
Outstanding shares	70,862,641	70,862,641	67,240,030	67,240,030
Effect of weighting changes in outstanding shares	(1,795,469)	(1,795,469)	(4,318,539)	(4,318,539)
Contingently issuable shares	(473,000)	(473,000)	-	-
Adjusted shares	68,594,172	68,594,172	62,921,491	62,921,491

There is no difference in basic and diluted loss per share related to 2008 or 2007. The net loss per common share for these periods excludes the effects of 59,793,178 and 35,691,194 common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of unvested restricted stock and common shares issuable upon exercise of outstanding stock options and warrants, or upon the conversion of convertible debt or convertible preferred stock.

## 4. Accounts Receivable and Concentrations of Credit Risk:

Accounts receivable at December 31, 2008 and 2007, net of allowance for doubtful accounts of \$1,000, consist of the following:

	2008	2007
Trade	\$ 1,602,919	\$ 1,609,690
Other	41,151	12,220
	\$ 1,644,070	\$ 1,621,910

At December 31, 2008 and 2007, approximately 93% and 94%, respectively, of net accounts receivable were 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.

## 5. Accrued Liabilities and Other:

Accrued liabilities at December 31, 2008 and 2007 consist of the following:

	2008	2007
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Contracted services and other	\$ 590,502	\$ 446,037
Compensation	220,487	207,904
Warranty reserve	72,643	115,395
Interest	18,000	9,409
Inventory purchases	16,044	23,204
	\$ 917,676	\$ 801,949

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## Notes to the Consolidated Financial Statements

## 6. 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, except in cases where the product has a limited use as designed. Our accrual for warranty expenses is adjusted periodically to reflect actual experience and is included in accrued liabilities on the consolidated balance sheets. 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' estimated reimbursement.

The activity in the warranty reserve account for the years ended December 31, 2008 and 2007 is as follows:

	2008	2007
Warranty reserve at beginning of year	\$ 115,395	\$ 44,858
Provision for warranty claims and changes in reserve for warranties	42,436	121,996
Payments charged against the reserve	(85,188)	(51,459)
Warranty reserve at end of year	\$ 72,643	\$ 115,395

## 7. Notes Payable:

In December 2004, we completed a private placement of four-year convertible promissory notes in an aggregate principal amount of \$8.1 million under a Securities Purchase Agreement 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 (collectively, the Great Point Funds). The notes originally bore interest at 8% per annum and were due on December 13, 2008. As part of the original transaction with the Great Point Funds, we issued the investors Series T warrants to purchase 10,125,000 shares of our common stock at an exercise price of \$0.46 per share, expiring in December 2009. In connection with this financing, we also issued Series U warrants to purchase 1,600,000 shares of 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 investors and the value of the beneficial conversion feature were recorded as discounts on the note and were being amortized over the term of the notes using the effective interest method. The fair value of the warrants issued to the placement agents was recorded as a deferred debt issuance cost and was also being amortized over the term of the notes using the effective interest method. In November 2006, we amended the Agreement and modified several of the key terms in the related notes, including the interest rate which was increased to 12% per annum, and modified the maturity of the notes to provide for a series of scheduled payments due on approximately six month intervals through January 7, 2009. We were also required to make additional mandatory repayments of principal to the Great Point Funds under certain circumstances. During 2007, we made scheduled principal payments and mandatory repayments totaling \$2.4 million.

In exchange for the increased interest rate and accelerated principal repayment schedule, the note holders eliminated the financial covenants under the original notes and eliminated certain conversion price adjustments from the original notes related to sales of equity securities by Neoprobe. We treated the amendment to the Agreement as a modification for accounting purposes, and the amortization of debt discount and issuance costs using the effective interest method was revised accordingly. During the third quarter of 2007, management determined that we had, from the date of the modification of the notes payable on November 30, 2006, through June 30, 2007, incorrectly applied the effective interest method in calculating the amortization of the debt discount and issuance costs related to the notes. As a result of the error in calculation, we recorded a total adjustment of \$286,000 in non-cash interest expense related to the

seven months ended June 30, 2007 in our results of operations for the third quarter of 2007. We determined that the net effect of this adjustment was not material, either quantitatively or qualitatively, to our results of operations and would not have resulted in changes to net loss per share, as reported, for the year ended December 31, 2006 or for the quarters ended March 31, 2007 and June 30, 2007. Recording the adjustment did not require amendment of the previously filed reports for the periods affected.

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## Notes to the Consolidated Financial Statements

In July 2007, David C. Bupp, our President and CEO, and certain members of his family (the Bupp Investors) purchased a \$1.0 million convertible note (the Bupp Note) and warrants. The note bears interest at 10% per annum, had an original term of one year and is repayable in whole or in part with no penalty. The note is convertible, at the option of the Bupp Investors, into shares of our common stock at a price of \$0.31 per share, a 25% premium to the average closing market price of our common stock for the 5 days preceding the closing of the transaction. As part of this transaction, we issued the Bupp Investors Series V warrants to purchase 500,000 shares of our common stock at an exercise price of \$0.31 per share, expiring in July 2012. The fair value of the warrants issued to the investors was approximately \$80,000 on the date of issuance and was determined using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 4.95%, volatility of 105% and no expected dividend rate. The value of the beneficial conversion feature of the note was estimated at \$86,000 based on the effective conversion price at the date of issuance. The fair value of the warrants issued to the investors and the value of the beneficial conversion feature were recorded as discounts on the note. We incurred \$43,000 of costs related to completing the Bupp financing, which were recorded in other assets. The discounts and the deferred debt issuance costs were being amortized over the term of the note using the effective interest method.

In December 2007, we executed a Securities Purchase Agreement (SPA) with Platinum Montaur Life Sciences, LLC (Montaur), pursuant to which we issued Montaur: (1) a 10% Series A Convertible Senior Secured Promissory Note in the principal amount of \$7,000,000, due December 26, 2011 (the Series A Note); and (2) a Series W warrant to purchase 6,000,000 shares of our common stock at an exercise price of \$0.32 per share, expiring in December 2012 (the Series W warrant). Additionally, pursuant to the terms of the SPA: (1) upon commencement of the Phase 3 clinical studies of Lymphoseek, we agreed to issue to Montaur a 10% Series B Convertible Senior Secured Promissory Note, due December 26, 2011 (the Series B Note, and hereinafter referred to collectively with the Series A Note as the Montaur Notes), and a five-year warrant to purchase an amount of common stock equal to the number of shares into which Montaur may convert the Series B Note, at an exercise price of 115% of the conversion price of the Series B Note (the Series X warrant), for an aggregate purchase price of \$3,000,000; and (2) upon completion of enrollment of 200 patients in the Phase 3 clinical studies of Lymphoseek, we agreed to issue to Montaur 3,000 shares of our 8% Series A Cumulative Convertible Preferred Stock (the Preferred Stock) and a five-year warrant to purchase an amount of common stock equal to the number of shares into which Montaur may convert the Preferred Stock, at an exercise price of 115% of the conversion price of the Preferred Stock (the Series Y warrant, and hereinafter referred to collectively with the Series W warrant and Series X warrant as the Montaur warrants), also for an aggregate purchase price of \$3,000,000. See Note 9.

The Series A Note bears interest at 10% per annum and is partially convertible at the option of Montaur into common stock at a price of \$0.26 per share. Interest is payable monthly, in arrears, beginning February 2008 until the earlier of the maturity date or the date of conversion. At our discretion, we may pay the monthly interest payments in cash, common stock, or a combination of cash and common stock, subject to certain limitations set forth in the Series A Note. According to the provisions of the Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series A 8% Cumulative Convertible Preferred Stock (the Certificate of Designations), Montaur may convert all or any portion of the shares of Preferred Stock into a number of shares of common stock equal to the quotient of: (1) the Liquidation Preference Amount of the shares of Preferred Stock by (2) the Conversion Price then in effect for the Preferred Stock. Per the Certificate of Designations, the Liquidation Preference Amount is equal to \$1,000 per share of Preferred Stock, and the Conversion Price is equal to the lesser of \$0.50 or the closing price of the common stock on the issuance date of the Preferred Stock, subject to adjustment as described in the Certificate of Designations.





## Notes to the Consolidated Financial Statements

Under the terms of the original Registration Rights Agreement, dated December 26, 2007, we agreed to file a registration statement with the Commission registering the shares of common stock underlying the Notes, the Preferred Stock and the warrants issued to Montaur pursuant to the SPA. On April 16, 2008, we entered into the Second Amendment to Registration Rights Agreement (the Second Amendment), pursuant to which Montaur agreed to limit our registration obligations to (a) the shares of common stock issuable upon conversion of the Series B Note; (b) the shares of common stock issuable upon exercise of the Series W and X warrants; and (c) 3,500,000 shares of common stock issuable as interest on the Montaur Notes. On July 10, 2008, we entered into a Third Amendment to Registration Rights Agreement (the Third Amendment), pursuant to which Montaur agreed to further limit our registration obligations to: (a) the shares of common stock issuable upon conversion of the Series B Note; (b) the shares of common stock issuable upon exercise of the Series X warrant; and (c) 3,500,000 shares of common stock issuable as interest on the Montaur Notes. Additionally, pursuant to the terms of the Registration Rights Agreement, as amended by the Second Amendment and Third Amendment, we agreed that: (a) within thirty-five (35) days following the Third Closing Date (as that term is defined in the SPA) we will prepare and file with the Commission an additional "resale" registration statement providing for the resale of (in the following order of priority): (i) the shares of common stock issuable upon the conversion of the Preferred Shares; (ii) the shares of common stock issuable upon exercise of the Series Y warrant; and (iii) shares of common stock issuable as dividends on the Preferred Stock, for an offering to be made on a continuous basis pursuant to Rule 415, and (b) within thirty-five (35) days of a receipt by the written request of the Holder therefore, we will prepare and file with the Commission an additional "resale" Registration Statement providing for the resale of the shares of common stock issuable upon the conversion of the Series A Note, and the shares of common stock issuable upon the exercise of the Series W warrant.

In accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, the conversion option and two put options were considered derivative instruments and were required to be bifurcated from the Series A Note and accounted for separately. In addition, in accordance with SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, the Series W warrant was accounted for as a liability due to the existence of certain provisions in the instrument. As a result, we recorded a total aggregate derivative liability of \$2.6 million on the date of issuance of the Series A Note and Series W warrant. The fair value of the bifurcated conversion option and put options was approximately \$1.45 million on the date of issuance. The fair value of the Series W warrant was approximately \$1.15 million on the date of issuance and was determined using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.7%, volatility of 94% and no expected dividend rate. Changes in the fair value of the derivative liabilities are recorded in the consolidated statement of operations. As of December 31, 2007, the derivative liabilities had estimated fair values of \$1.60 million and \$1.25 million for the conversion and put options and the warrants, respectively.

On March 14, 2008, Neoprobe and Montaur executed amendments to the Series A Note and the Series W warrant. The amendments eliminated certain minor cash-based penalty provisions in the Series A Note and Series W warrant which entitled the holders to different compensation than our common shareholders under certain circumstances and qualifying Triggering Events. The provisions that were eliminated and/or modified were the provisions that led to the derivative accounting treatment for the embedded conversion option in the Series A Note and the Series W warrant. Because the value of our stock increased between December 31, 2007, our year end, and March 14, 2008, the effect of marking the conversion option and warrant liabilities to "market" at March 14, 2008 resulted in an increase in the estimated fair value of the conversion option and warrant liabilities of \$381,000 which was recorded as non-cash expense during the first quarter of 2008. The estimated fair value of the conversion option and warrant liabilities of \$2.9 million was reclassified to additional paid-in capital during the first quarter of 2008 as a result of the amendments. The effect of marking the put option liabilities related to the Series A Note to "market" at March 31, June 30, September 30 and December 31, 2008 resulted in a net increase in the estimated fair value of the put option liabilities of \$51,000 which was recorded as non-cash expense during 2008. The estimated fair value of the

put option liabilities related to the Series A Note of \$360,000 remained classified as derivative liabilities as of December 31, 2008.

The initial aggregate fair value of the conversion option and the put options related to the Series A Note and the fair value of the Series W warrant of \$2.6 million were recorded as a discount on the note and are being amortized over the term of the note using the effective interest method. During 2008, we recorded interest expense of \$543,000 related to the amortization of the debt discount. We incurred \$510,000 of costs related to completing the initial Montaur financing, which were recorded in other assets on the consolidated balance sheet. The deferred financing costs are being amortized using the effective interest method over the term of the note. During 2008, we recorded interest expense of \$106,000 related to the amortization of the deferred financing costs.

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## Notes to the Consolidated Financial Statements

In April 2008, we completed the second closing under the December 2007 Montaur Purchase Agreement, as amended, pursuant to which we issued Montaur a 10% Series B Convertible Senior Secured Promissory Note in the principal amount of \$3,000,000, due December 26, 2011; and a Series X warrant to purchase 8,333,333 shares of our common stock at an exercise price of \$0.46 per share, expiring in April 2013. The Series B Note bears interest at 10% per annum and is fully convertible at the option of Montaur into common stock at a price of \$0.36 per share. Interest is payable monthly, in arrears, beginning in April 2008 until the earlier of the maturity date or the date of conversion. At our discretion, we may pay the monthly interest payments in cash, common stock, or a combination of cash and common stock, subject to certain limitations set forth in the Series B Note.

The fair value of the Series X warrant was approximately \$1.28 million on the date of issuance and was determined using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.6%, volatility of 95% and no expected dividend rate. The value of the beneficial conversion feature of the Series B Note was estimated at \$1.44 million based on the effective conversion price at the date of issuance. The fair value of the warrant issued to the investors and the value of the beneficial conversion feature were recorded as discounts on the note and are being amortized over the term of the note using the effective interest method. The two put options were considered derivative instruments and were required to be bifurcated from the Series B Note and accounted for separately. The fair value of the bifurcated put options was approximately \$258,000 on the date of issuance. Changes in the fair value of the derivative liabilities are recorded in the consolidated statement of operations. The effect of marking the put option liabilities related to the Series B Note to "market" at June 30, September 30 and December 31, 2008 resulted in a net increase in the estimated fair value of the put option liabilities of \$20,000 which was recorded as non-cash expense during 2008. The estimated fair value of the put option liabilities related to the Series B Note of \$277,000 remained classified as derivative liabilities as of December 31, 2008.

The initial aggregate fair value of the beneficial conversion feature and put options related to the Series B Note, and the fair value of the Series X warrant of \$2.98 million were recorded as discounts on the note and are being amortized over the term of the note using the effective interest method. During 2008, we recorded interest expense of \$33,000 related to the amortization of the debt discount. We incurred \$188,000 of costs related to completing the second Montaur financing, which were recorded in other assets on the consolidated balance sheet. The deferred financing costs are being amortized using the effective interest method over the term of the note. During 2008, we recorded interest expense of \$2,000 related to the amortization of the deferred financing costs.

In connection with the second closing, we also amended the SPA with respect to the milestone that would trigger the third closing for an additional \$3 million investment from Montaur. The milestone was revised from the accrual of 200 patients in a Phase 3 trial for Lymphoseek to obtaining 135 vital blue dye lymph nodes from patients with breast cancer or melanoma who have completed surgery with the injection of the drug in a Phase 3 clinical trial of Lymphoseek.

In connection with the SPA, Montaur requested that the term of the \$1.0 million Bupp Note be extended until at least one day following the maturity date of the Montaur Notes. In consideration for the Bupp Investors' agreement to extend the term of the Bupp Note pursuant to an Amendment to the Bupp Purchase Agreement, dated December 26, 2007, we agreed to provide security for the obligations evidenced by the Amended 10% Convertible Note in the principal amount of \$1,000,000, due December 31, 2011, executed by Neoprobe in favor of the Bupp Investors (the Amended Bupp Note), under the terms of a Security Agreement, dated December 26, 2007, by and between Neoprobe and the Bupp Investors (the Bupp Security Agreement). As further consideration for extending the term of the Bupp Note, we issued the Bupp Investors Series V warrants to purchase 500,000 shares of our common stock at an exercise price of \$0.32 per share, expiring in December 2012. The fair value of the warrants issued to the Bupp Investors was approximately \$96,000 on the date of issuance and was determined using the Black-Scholes option pricing model with

the following assumptions: an average risk-free interest rate of 3.72%, volatility of 94% and no expected dividend rate. The fair value of the warrants was recorded as a discount on the note and is being amortized over the term of the note using the effective interest method. We treated the amendment to the Bupp Note as an extinguishment of debt for accounting purposes. As such, the remaining discount resulting from the fair value of the warrants and the value of the beneficial conversion feature and the remaining unamortized deferred financing costs associated with the original note were written off as a loss on extinguishment of debt in December 2007.

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## Notes to the Consolidated Financial Statements

We applied \$5,725,000 from the proceeds of our issuance of the Series A Note and Series W warrant to the complete and total satisfaction of our outstanding obligations under the Replacement Series A Convertible Promissory Notes issued to the Great Point Funds and David C. Bupp as of November 30, 2006, pursuant to the Securities Purchase Agreement, dated as of December 13, 2004, by and among Neoprobe, the Great Point Funds and Mr. Bupp, as amended by the Amendment dated as of November 30, 2006 (the Amended GPP Purchase Agreement). We treated the early repayment of the notes as an extinguishment of debt for accounting purposes. As such, the remaining discount resulting from the fair value of the warrants and the value of the beneficial conversion feature associated with the original notes was written off as a loss on extinguishment of debt in December 2007. We applied an additional \$675,000 from the proceeds of our issuance of the Series A Note and Series W warrant to the redemption of Series T warrants to purchase 10,000,000 shares of our common stock at an exercise price of \$0.46 per share, issued to the Great Point Funds pursuant to the Amended GPP Purchase Agreement. In connection with the consummation of the Montaur Purchase Agreement and amendment of the Bupp Purchase Agreement, Mr. Bupp agreed to the cancellation of Series T warrants to purchase 125,000 shares of our common stock at an exercise price of \$0.46 per share, originally issued to Mr. Bupp pursuant to the Amended GPP Purchase Agreement. The combined events retired all of the Series T warrants issued to the Great Point Funds and Mr. Bupp.

## 8. Income Taxes:

As of December 31, 2008 and 2007, our deferred tax assets in the U.S. were approximately \$37.8 million and \$40.1 million, respectively, prior to any limitations under Sections 382 and 383 of the Internal Revenue Code (IRC), as discussed below. The components of our deferred tax assets, pursuant to SFAS No. 109, Accounting for Income Taxes, are summarized as follows:

	As of December 31,	
	2008	2007
<b>Deferred tax assets:</b>		
Federal net operating loss carryforwards	\$ 30,071,041	\$ 32,428,173
State net operating loss carryforwards	1,945,601	2,229,635
R&D credit carryforwards	4,781,584	4,906,697
Temporary differences	979,828	552,981
Deferred tax assets before valuation allowance	37,778,055	40,117,486
Valuation allowance	(37,778,055)	(40,117,486)
Net deferred tax assets	\$ -	\$ -

SFAS No. 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. Due to the uncertainty surrounding the realization of these deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2008 and 2007.

As of December 31, 2008 and 2007, CardioSonix had deferred tax assets in Israel of approximately \$2 million, primarily related to net operating loss carryforwards 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 deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2008 and 2007. 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 (i.e., 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. As of January 1, 2009, SFAS No. 141(R), Business Combinations, amends the income tax accounting guidance to require that reduction in the amount of an acquired valuation allowance be recorded as a reduction of income tax expense.

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## Notes to the Consolidated Financial Statements

Under Sections 382 and 383 of the 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 will likely be significantly limited under certain circumstances.

Reconciliations between the statutory federal income tax rate and our effective tax rate are as follows:

	Years Ended December 31,			
	2008		2007	
	Amount	%	Amount	%
Benefit at statutory rate	\$ (1,756,517)	(34.0)%	\$ (1,729,992)	(34.0)%
Adjustments to valuation allowance	1,582,238	30.6%	1,502,950	29.5%
Other	174,279	3.4%	227,042	4.5%
Benefit per financial statements	\$ -		\$ -	

Deferred tax assets of \$3.7 million related to net operating loss carryforwards and \$657,000 related to R&D credit carryforwards expired during 2008.

#### 9. Preferred Stock:

In December 2007, we entered into a SPA with Montaur, pursuant to which we issued Montaur a 10% Series A Note in the principal amount of \$7,000,000, due December 26, 2011, and a five-year Series W warrant to purchase 6,000,000 shares of our common stock at an exercise price of \$0.32 per share. Montaur may convert \$3.5 million of the Series A Note into shares of common stock at the conversion price of \$0.26 per share. The SPA also provided for two further tranches of financing, a second tranche of \$3 million in exchange for a 10% Series B Note along with a five year Series X warrant to purchase shares of our common stock, and a third tranche of \$3 million in exchange for 3,000 shares of our 8% Preferred Stock and a five-year Series Y warrant to purchase shares of our common stock. Closing of the second and third tranches were subject to the satisfaction by the Company of certain milestones related to the progress of the Phase 3 clinical trials of our Lymphoseek radiopharmaceutical product. See Notes 7 and 10(a).

In December 2008, after we obtained 135 vital blue dye lymph nodes from patients who had completed surgery and the injection of the drug in a Phase 3 clinical trial of Lymphoseek in patients with breast cancer or melanoma, we issued Montaur 3,000 shares of our 8% Preferred Stock and a five-year Series Y warrant to purchase 6,000,000 shares of our common stock, at an exercise price of \$0.575 per share, for an aggregate purchase price of \$3,000,000. Montaur may convert each share of the Preferred Stock into a number of shares of our common stock equal to the quotient of (a) the Liquidation Preference Amount of the shares of Preferred Stock by (b) the Conversion Price. The "Liquidation Preference Amount" for the Preferred Stock is \$1,000 and the "Conversion Price" of the Preferred Stock was set at \$0.50 on the date of issuance, thereby making the shares of Preferred Stock convertible into an aggregate 6,000,000 shares of our common stock, subject to adjustment as described in the Certificate of Designations. We may elect to pay dividends due to Montaur on the shares of Preferred Stock in registered shares of common stock. The number of shares of common stock to be applied against any such dividend payment will be determined by reference to the quotient of (a) the applicable dividend payment by (b) the average daily volume weighted average price of our common stock on the OTC Bulletin Board (or national securities exchange, if applicable) as reported by Bloomberg Financial L.P. for the five days upon which our common stock is traded on the OTC Bulletin Board immediately preceding the date of the dividend payment.





## Notes to the Consolidated Financial Statements

Pursuant to the terms of a Registration Rights Agreement, dated December 26, 2007, as amended by the Amendment to Registration Rights Agreement, dated February 7, 2008, Second Amendment to Registration Rights Agreement, dated April 16, 2008, Third Amendment to Registration Rights Agreement, dated July 10, 2008, and Fourth Amendment to Registration Rights Agreement, dated December 5, 2008, we agreed to file a post-effective amendment to the registration statement providing for the: (a) deregistration of shares of common stock issuable upon the conversion of the Series B Note and the shares of common stock issuable upon the exercise of the Series X warrant; and (b) registration of the resale of: (i) the shares of common stock issuable upon conversion of the Preferred Stock; (ii) the shares of common stock issuable upon exercise of the Series Y warrant; (iii) 3,500,000 shares of common stock issuable as interest or dividends on the Montaur Notes and the Preferred Stock; and (iv) up to 4,666,666 shares issuable upon the conversion of the Series B Note, provided that the total number of shares of common stock registered would not exceed 20,166,666. Additionally, we agreed that within thirty-five days of receipt from Montaur of written request therefor, we would prepare and file an additional "resale" registration statement providing for the resale of: (i) the shares of common stock issuable upon the conversion of the Series A Note; (ii) the shares of common stock issuable upon the exercise of the Series W warrant; (iii) any unregistered shares of common stock issuable upon the conversion of the Series B Note; and (iv) the shares of common stock issuable upon the exercise of the Series X warrant, provided, however, that we are not required to file such additional registration statement, or may exclude shares from such additional registration statement, if we believe in good faith, based upon advice from the Securities and Exchange Commission's Staff, that application of Rule 415 would not permit registration of all or the excluded portion of such shares.

The fair value of the Series Y warrant was approximately \$2.07 million on the date of issuance and was determined using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 1.7%, volatility of 74% and no expected dividend rate. The relative fair value of the warrant, the amount recorded to equity in accordance with Accounting Principles Board Opinion No. 14, Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants, was \$1.13 million. The value of the beneficial conversion feature of the Preferred Stock was estimated at \$1.55 million based on the effective conversion price at the date of issuance. The put option was considered a derivative instrument and was required to be bifurcated from the Preferred Stock and accounted for separately. The fair value of the bifurcated put option was approximately \$216,000 on the date of issuance. Changes in the fair value of the derivative liability are recorded in the consolidated statement of operations. The estimated fair value of the put option liability related to the Preferred Stock of \$216,000 remained classified as a derivative liability as of December 31, 2008.

In accordance with EITF Topic D-98, Classification and Measurement of Redeemable Securities, the preferred stock was classified as temporary equity as the shares are subject to redemption under the contingent put option. The initial relative fair value of the Series Y warrant of \$1.13 million and the initial intrinsic value of the beneficial conversion feature and put option related to the Preferred Stock were recorded as deemed distributions and added to the accumulated deficit. We incurred \$180,000 of costs related to completing the third Montaur financing, which were recorded as a reduction of additional paid-in capital on the consolidated balance sheet.

10. Equity:

- a. Stock Warrants: At December 31, 2008, there are 23.4 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from \$0.31 to \$0.85 per share with a weighted average exercise price per share of \$0.45.

The following table summarizes information about our outstanding warrants at December 31, 2008:

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	Exercise Price	Number of Warrants	Expiration Date
Series Q	\$ 0.50	375,000	March 2009
Series U	\$ 0.46	1,600,000	December 2009
Series V	\$ 0.31	500,000	July 2012
Series V	\$ 0.32	500,000	December 2012
Series W	\$ 0.32	6,000,000	December 2012
Series X	\$ 0.46	8,333,333	April 2013
Series Y	\$ 0.575	6,000,000	December 2013
Series Z	\$ 0.70	60,000	August 2013
Series Z	\$ 0.85	60,000	August 2013
	\$ 0.45	23,428,333	

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## Notes to the Consolidated Financial Statements

In April 2003, we completed bridge loans with our President and CEO, David Bupp, and an outside investor. In connection with these loans, we issued a total of 875,000 Series Q warrants to purchase our common stock at an exercise price of \$0.13 per share, expiring in April 2008. In March 2004, at the request of our Board of Directors, Mr. Bupp agreed to extend the due date of his loan. In exchange for extending the due date of his loan, we issued Mr. Bupp an additional 375,000 Series Q warrants to purchase our common stock at an exercise price of \$0.50 per share, expiring in March 2009. During 2008, Mr. Bupp exercised 375,000 Series Q warrants in exchange for issuance of 375,000 shares of our common stock, resulting in gross proceeds of \$48,750. In addition, the outside investor exercised 500,000 Series Q warrants in exchange for issuance of 500,000 shares of our common stock, resulting in gross proceeds of \$65,000. At December 31, 2008, 375,000 Series Q warrants related to the bridge loan from Mr. Bupp remained outstanding. See Note 17(b).

In November 2003, we executed common stock purchase agreements with certain investors. In connection with these agreements, we issued the purchasers 6,086,959 Series R warrants to purchase our common stock at an exercise price of \$0.28 per share, expiring in October 2008, and issued the placement agents 1,354,348 Series S warrants to purchase our common stock on similar terms. During 2008, an outside investor exercised a total of 200,200 Series R warrants in exchange for issuance of 200,200 shares of our common stock, resulting in gross proceeds of \$56,056. In addition, certain outside investors exercised a total of 2,658,698 Series R warrants and 644,565 Series S warrants on a cashless basis in exchange for issuance of 1,289,990 shares of our common stock. No Series R or Series S warrants were exercised during 2007. At December 31, 2008, no Series R or Series S warrants remained outstanding.

In August 2008, we executed consulting agreements with certain investor advisory service firms. In connection with these agreements, we issued the consultants 60,000 Series Z warrants to purchase our common stock at an exercise price of \$0.70 per share and 60,000 Series Z warrants to purchase our common stock at an exercise price of \$0.85 per share, expiring in August 2013. All 120,000 Series Z warrants remained outstanding at December 31, 2008.

See Note 7 for a discussion of Series U, V, W and X warrants. See Notes 7 and 9 for a discussion of the Series Y warrant.

b. Common Stock Purchase Agreement: In December 2006, we entered into a Common Stock Purchase Agreement with Fusion Capital, an Illinois limited liability company, to sell \$6.0 million of our common stock to Fusion Capital over a 24-month period which ended on November 21, 2008. Through November 21, 2008, we sold to Fusion Capital 7,568,671 shares for proceeds of \$1.9 million under the agreement. We have not sold any shares under the agreement since November 13, 2007. In December 2008, we entered into the First Amendment to the Common Stock Purchase Agreement (the First Amendment) which gave us a right to sell to Fusion Capital before March 1, 2011, an additional \$6.0 million of our common stock along with the \$4.1 million of the unsold balance of the \$6.0 million we originally had the right to sell to Fusion Capital under the agreement prior to the First Amendment. After giving effect to the First Amendment, the remaining aggregate amount of our common stock we can now sell to Fusion Capital is \$10.1 million. In respect of sales to Fusion Capital that we may make in the future under the agreement as amended, we have authorized a total of 10,654,000 shares of our common stock for sale to Fusion Capital.

In December 2006, we issued to Fusion Capital 720,000 shares of our common stock as a commitment fee upon execution of the agreement. In connection with sales of our common stock, we issued an additional 234,000 shares of our common stock to Fusion Capital as an additional commitment fee. In connection with entering into the First Amendment, we issued an additional 360,000 shares in consideration for Fusion Capital's entering into the amendment. Also, under the agreement, as an additional commitment fee we have agreed to issue to Fusion Capital pro rata an additional 486,000 shares of our common stock as we sell the first \$4.1 million of our common stock to

Fusion Capital under the agreement as amended.

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## Notes to the Consolidated Financial Statements

c. Common Stock Reserved: As of December 31, 2008, we have reserved 59,793,178 shares of authorized common stock for the exercise of all outstanding options, warrants, convertible debt, and convertible preferred stock.

## 11. Segments and Subsidiary Information:

a. Segments: We report information about our operating segments using the “management approach” in accordance with SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. We own or have rights to intellectual property involving two primary types of medical device products, including gamma detection instruments currently used primarily in the application of SLNB, and blood flow measurement devices. We also own or have rights to intellectual property related to several drug and therapy products.

The information in the following table is derived directly from each reportable segment’s financial reporting.

(\$ amounts in thousands) 2008	Gamma Detection Devices	Blood Flow Devices	Drug and Therapy Products	Corporate	Total
Net sales:					
United States <sup>1</sup>	\$ 7,422	\$ 101	\$ -	\$ -	\$ 7,523
International	167	196	-	-	363
Research and development expenses	949	219	3,338	-	4,506
Selling, general and administrative expenses, excluding depreciation and amortization <sup>2</sup>	17	188	-	2,798	3,004
Depreciation and amortization	120	241	2	46	408
Income (loss) from operations <sup>3</sup>	3,658	(516)	(3,340)	(2,844)	(3,042)
Other income (expense) <sup>4</sup>	-	-	-	(2,124)	(2,124)
Total assets, net of depreciation and amortization:					
United States operations	2,410	491	25	5,336	8,262
Israeli operations (Cardiosonix Ltd.)	-	1,357	-	-	1,357
Capital expenditures	9	-	18	89	116

(\$ amounts in thousands) 2007	Gamma Detection Devices	Blood Flow Devices	Drug and Therapy Products	Corporate	Total
Net sales					
United States <sup>1</sup>	\$ 6,577	\$ 166	\$ -	\$ -	\$ 6,743
International	197	185	-	-	382
Research and development expenses	680	359	1,827	-	2,866
Selling, general and administrative expenses, excluding depreciation	-	-	-	2,432	2,432

and amortization <sup>2</sup>					
Depreciation and amortization	99	262	-	44	405
Income (loss) from operations <sup>3</sup>	3,093	(552)	(1,827)	(2,477)	(1,763)
Other income (expense) <sup>4</sup>	-	-	-	(3,325)	(3,325)
Total assets, net of depreciation and amortization:					
United States operations	2,280	703	186	2,334	5,503
Israeli operations (Cardiosonix Ltd.)	-	1,560	-	-	1,560
Capital expenditures	16	9	-	16	41

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

2 General and administrative costs, excluding depreciation and amortization, represent costs that relate to the general administration of the Company and as such are not currently allocated to our individual reportable segments.

3 Income (loss) from operations does not reflect the allocation of selling, general and administrative costs to our individual reportable segments.

4 Amounts consist primarily of interest income and interest expense which are currently not allocated to our individual reportable segments.

Notes to the Consolidated Financial Statements

b. Subsidiary: On December 31, 2001, we acquired 100 percent of the outstanding common shares of Cardiosonix, an Israeli company. 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's operations have been included in our consolidated results from the date of acquisition.

12. Agreements:

a. Supply Agreement: In February 2004, we entered into a product supply agreement with TriVirix International (TriVirix) for the manufacture of certain of our medical device products. The term of this agreement expired in February 2008, but was automatically extended through February 2009, and may continue to be automatically extended for successive one-year periods. Either party has the right to terminate the agreement at any time upon 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 \$1.5 million and \$1.2 million for the years ended December 31, 2008 and 2007, respectively. As of December 31, 2008, we have issued purchase orders under the agreement with TriVirix for \$1.7 million of our products for delivery through December 2009.

b. Marketing and Distribution Agreement: During 1999, we entered into a distribution agreement with EES covering our gamma detection devices used in surgical radiation detection. The initial five-year term expired December 31, 2004, with options to extend for two successive two-year terms. In March 2006, EES exercised its option for a second two-year term extension of the distribution agreement covering our gamma detection devices, thus extending the distribution agreement through the end of 2008. In December 2007, Neoprobe and EES executed an amendment to the distribution agreement which extended the agreement through the end of 2013. Under the agreement, we manufacture and sell our current line of gamma detection device 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 SLNB intellectual property to make and sell other products that may be developed using our SLNB 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. As consideration for extending the distribution agreement through the end of 2013, EES paid us \$500,000 in December 2007, representing a non-refundable license fee and reimbursement of past research and development expenses. We intend to recognize the \$500,000 payment as revenue on a straight-line basis over the extended term of the agreement, or January 2009 through December 2013. 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 SLNB intellectual property. In addition, we are entitled to a royalty on any SLNB product commercialized by EES that does not infringe any of our existing intellectual property.

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## Notes to the Consolidated Financial Statements

c. Research and Development Agreements: Cardiosonix's 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 of \$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. In January 2006, the OCS consented to the transfer of manufacturing as long as we comply with the terms of the OCS statutes under Israeli law. As long as we maintain at least 10% Israeli content in our blood flow devices, we will pay a royalty rate of 4% on sales of applicable blood flow devices and must repay the OCS a total of \$1.2 million in royalties. However, should the amount of Israeli content of our blood flow device products decrease below 10%, the royalty rate could increase to 5% and the total royalty payments due could increase to \$2.3 million. As such, the total amount we will have to repay the OCS will likely be 150% to 300% of the amounts of the original grants. Through December 2008, we have paid the OCS a total of \$66,000 in royalties related to sales of products developed under this program. As of December 31, 2008, we have accrued obligations for royalties totaling \$6,000.

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 SLNB 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 commencement of clinical trials and 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 \$35,000 and \$45,000 in 2008 and 2007, respectively, and were recorded in research and development expenses.

UCSD has the right to terminate the agreement or change the nature of the agreement to a non-exclusive agreement if it is determined that we have not been diligent in developing and commercializing the covered products, marketing the products within six months of receiving regulatory approval, reasonably filling market demand or obtaining all the necessary government approvals.

During April 2005, we completed an evaluation license agreement with UCSD expanding the field of use for the proprietary compound developed by UCSD researchers. The expanded field of use will allow Lymphoseek to be developed as an optical or ultrasound agent. The evaluation license agreement was effective until March 31, 2007. Under the terms of the agreement, UCSD granted us limited rights to make and use licensed products as defined in the agreement and to practice the defined licensed methods during the term of the agreement for the sole purpose of evaluating our interest in negotiating a commercial license. 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 an initial evaluation license fee of \$36,000 and evaluation license maintenance fees of \$9,000 payable on the first year anniversary of the effective date, \$9,000 payable on the eighteen-month anniversary of the effective date, and \$18,000 payable prior to termination. We also agreed to pay UCSD fifty percent of any sublicense fees and to

reimburse UCSD for all patent-related costs. In March 2007, we executed a second evaluation license agreement which was effective until March 31, 2008. In consideration for the license rights, we agreed to pay UCSD an initial evaluation license fee of \$20,000 and evaluation license maintenance fees of \$10,000 payable on the six-month anniversary of the effective date and \$10,000 payable on the twelve-month anniversary of the effective date. We also agreed to pay UCSD fifty percent of any sublicense fees and to reimburse UCSD for all patent-related costs. Total costs related to the UCSD evaluation license agreements were \$10,000 and \$53,000 in 2008 and 2007, respectively, and were recorded in research and development expenses.

Notes to the Consolidated Financial Statements

During April 2008, we completed a license agreement with UCSD for an expanded field of use allowing Lymphoseek to be developed as an optical or ultrasound agent. The license agreement is effective until the expiration date of the longest-lived underlying patent. 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 certain sublicense terms as defined in the agreement. 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 commencement of clinical trials and 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 \$37,000 in 2008 and were recorded in research and development expenses.

During January 2005, we executed a license agreement with The Ohio State University (OSU), Cira LLC, and Cira Bio for certain technology relating to activated cellular therapy. The license agreement is effective until the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, OSU has granted the licensees the exclusive rights to make, have made, use, lease, sell and import licensed products as defined in the agreement and to utilize the defined licensed practices. We may also sublicense the patent rights. In consideration for the license rights, we agreed to pay OSU a license fee of \$5,000 on January 31, 2006. We also agreed to pay OSU additional license fees related to initiation of Phase 2 and Phase 3 clinical trials, a royalty on net sales of licensed products subject to a minimum annual royalty of \$100,000 beginning in 2012, and a percentage of any non-royalty license income. Also during January 2005, we completed a business venture agreement with Cira LLC that defines each party's responsibilities and commitments with respect to Cira Bio and the license agreement with OSU. In connection with the execution of the option, Cira Ltd. also agreed to assign all interests in the ACT technology in the event of the closing of such a financing transaction.

- d. **Employment Agreements:** We maintain employment agreements with five of our officers. The employment agreements contain change in control provisions that would entitle each of the officers to 1 to 2.5 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. As of December 31, 2008, our maximum contingent liability under these agreements in such an event is approximately \$2.0 million. The employment agreements also provide for severance, disability and death benefits. See Note 17(c).

13. **Leases:**

We lease certain office equipment under capital leases which expire from 2009 to 2011. We also lease office space under an operating lease that expires in January 2013.

## Notes to the Consolidated Financial Statements

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

	Capital Leases	Operating Leases
2009	\$ 10,382	\$ 98,465
2010	7,897	101,285
2011	3,948	104,105
2012	-	106,925
2013	-	8,930
	22,227	\$ 419,710
Less amount representing interest	2,048	
Present value of net minimum lease payments	20,179	
Less current portion	9,084	
Capital lease obligations, excluding current portion	\$ 11,095	

Total rental expense was \$108,000 and \$153,000 for the years ended December 31, 2008 and 2007, respectively.

14. 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 \$33,000 and \$30,000 during 2008 and 2007, respectively, related to common stock contributed to the plan in 2009 and 2008, respectively.

15. Supplemental Disclosure for Statements of Cash Flows:

We paid interest aggregating \$1.0 million and \$869,000 for the years ended December 31, 2008 and 2007, respectively. During 2008 and 2007, we transferred \$182,000 and \$84,000, respectively, in inventory to fixed assets related to the creation and maintenance of a pool of service loaner equipment. Also during 2008 and 2007, we prepaid \$171,000 and \$160,000, respectively, in insurance through the issuance of notes payable to finance companies with weighted average interest rates of 6.6%. The note payable to a finance company issued in 2008 matures in July 2009. During 2008, we purchased equipment under a capital lease totaling \$20,000. No new equipment was leased during 2007.

16. 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.

17. Subsequent Events:

- a. Stock-Based Compensation: On January 5, 2009, the Compensation, Nominating and Governance (CNG) Committee of the Board of Directors granted 165,000 stock options with an exercise price of \$0.59 to employees and directors. Also on January 5, 2009, the CNG Committee granted 400,000 shares of restricted stock that will vest based on certain defined performance objectives to David C. Bupp, our President and CEO. In addition, on February 16, 2009, we granted 50,000 stock options with an exercise price of \$0.65 and 100,000 shares of restricted stock that will vest based on certain defined performance objectives to Frederick O. Cope, our Vice President,

Pharmaceutical Research and Clinical Development. On February 27, 2009, the CNG Committee granted 68,000 stock options with an exercise price of \$0.55 to employees. See Note 1(o).

## Notes to the Consolidated Financial Statements

- b. Warrant Exercises: During the first quarter of 2009, David C. Bupp, our President and CEO, exercised Series Q warrants resulting in the issuance of 50,000 shares of our common stock and from which we received gross proceeds of \$25,000. See Note 10(a).
- c. Employment Agreements: During January 2009, we entered into new employment agreements with six officers. The new agreements have substantially similar terms to the officers' previous agreements. See Note 12(d).

## 18. 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,				
	2008	2007	2006	2005	2004
<b>Statement of Operations Data:</b>					
Net sales	\$ 7,715	\$ 7,125	\$ 6,051	\$ 5,919	\$ 5,353
License and other revenue	172	-	-	-	600
Gross profit	4,876	3,940	3,419	3,543	3,608
Research and development expenses	4,506	2,866	3,803	4,032	2,454
Selling, general and administrative expenses	3,413	2,837	3,076	3,156	3,153
Loss from operations	(3,042)	(1,763)	(3,460)	(3,644)	(1,999)
Other expenses, net	(2,124)	(3,325)	(1,281)	(1,285)	(1,542)
Net loss	\$ (5,166)	\$ (5,088)	\$ (4,741)	\$ (4,929)	\$ (3,541)
<b>Loss per common share:</b>					
Basic	\$ (0.08)	\$ (0.08)	\$ (0.08)	\$ (0.08)	\$ (0.06)
Diluted	\$ (0.08)	\$ (0.08)	\$ (0.08)	\$ (0.08)	\$ (0.06)
<b>Shares used in computing loss per common share: (1)</b>					
Basic	68,594	62,921	58,587	58,434	56,764
Diluted	68,594	62,921	58,587	58,434	56,764

	As of December 31,				
	2008	2007	2006	2005	2004
<b>Balance Sheet Data:</b>					
Total assets	\$ 9,619	\$ 7,063	\$ 8,034	\$ 11,570	\$ 15,366
Long-term obligations	7,323	8,836	4,922	6,052	8,192
Accumulated deficit	(148,840)	(140,777)	(135,688)	(130,947)	(126,018)

(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 unvested restricted stock, convertible securities, options and warrants, if dilutive.