NEOPROBE CORP
Form 10-K
March 16, 2011

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

FORM 10-K

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

For the fiscal year ended December 31, 2010

or

¨ 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	31-1080091
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
425 Metro Place North, Suite 300, Dublin, Ohio	43017-1367
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (614) 793-7500

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, par value $.001 per share	NYSE Amex Equities
(Title of Class)	(Name of Each Exchange on Which Registered)

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

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 information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Yes ¨ No x

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 ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12-b-2 of the Act.)

Yes ¨ No x

The aggregate market value of shares of common stock held by non-affiliates of the registrant on June 30, 2010 was $142,554,910.

The number of shares of common stock outstanding on March 11, 2011 was 88,175,675.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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 oncology products that enhance patient care and improve patient benefit. 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 evaluations and discussions of the status of the regulatory pathway for our RIGScanTM product 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 at the beginning of 2002 through 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. As a result of our efforts over the last several years we have successfully re-established our core competency regarding

radiopharmaceutical development. We recently announced that we had enrolled an adequate number of subjects to enable us to meet the lymph node accrual goal for the second Phase 3 clinical trial for our lead radiopharmaceutical product candidate, Lymphoseek®, and as a result, we are now preparing to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA). Interest in, and activity related to, our original radiopharmaceutical initiative, RIGS, has also increased significantly in recent years following the receipt of formal scientific advice in late 2008 from the European Medicines Agency (EMA). We recently held a meeting with FDA that has clarified the regulatory and development process related to our RIGScan product. As a result of this meeting, we intend to implement additional manufacturing activities through 2011 as a first step to recommencing human clinical study of the technology in 2012 and beyond. Our subsidiary, Cira Biosciences, Inc. (Cira Bio), is also evaluating the market opportunities for yet another technology platform, activated cellular therapy (ACT).

The success we have been experiencing in recent years related to our drug development activities caused us, during 2009, to re-evaluate our product initiatives and strategies. As a result of this re-evaluation, we made the decision during the third quarter of 2009 to discontinue the operations of our blood flow measurement device product line. To date, we have been unsuccessful in our attempts to sell our Cardiosonix Ltd. subsidiary. As a result, we are taking additional steps to complete the shutdown of our blood flow measurement device business. We believe this decision will allow us to better focus on our pipeline development opportunities that better leverage our core competencies. We expect to continue utilizing a virtual business model to further our product and pipeline development that provides the opportunity for incremental return on the achievement of key development and funding milestones.

Our Technology

Gamma Detection Devices

Through 2010, 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 mounted 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 factory remanufacture. Our most recent software release enables our entire installed base of neoprobe GDS and neo2000 users to use our wireless gamma detection probes, based on Bluetooth® wireless technology, that have been commercially launched over the last few years. During 2009, we also introduced a new gamma detection probe capable of detecting higher energy isotopes such as F-18 fluorodeoxyglucose (18F FDG) that are frequently used in connection with Positron Emission Tomography (PET) scans. During early March of 2011, we introduced a 9mm wireless gamma detection probe further expanding our family of wireless probes to enable surgeons to address a broader range of surgical challenges. In addition, in February 2011 we licensed intellectual property that may be used to develop an intraoperative hand-held miniature gamma camera to be used in combination with either Lymphoseek or RIGScan products.

Surgeons use our gamma detection devices in a surgical application referred to as intraoperative lymphatic mapping (ILM or lymphatic mapping) or sentinel lymph node biopsy (SLNB). ILM 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. These lymph node(s), sometimes referred to as the "sentinel" node(s), may provide critical information about the stage of a patient’s disease. ILM begins when a patient is injected at the site of the main tumor with a commercially available radioactive tracing agent, with or without a blue dye. 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 radiotracer 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 ILM to solid tumor cancer treatment has been most widely developed in the breast cancer and melanoma indications. Numerous clinical studies, involving thousands of 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 ILM or 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 for our neoprobe GDS 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. Recently, important data regarding lymph node dissections were published in the Journal of the American Medical Association (JAMA, February 9, 2011) and in the New England Journal of Medicine (NEJM, January 19, 2011). We believe the information published in both articles continues to underscore the importance of effective SLNB in the staging and treatment of patients with solid tumor cancers. 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 continue to approach 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. In addition, we believe that a replacement device market in the gamma detection device sector is beginning to develop, 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.

Although lymphatic mapping has found its greatest acceptance thus far in breast cancer and melanoma, we believe that Lymphoseek may be instrumental in extending ILM 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 due, we believe, to limitations associated with currently available radioactive tracing agents; however, we believe our development of Lymphoseek may positively impact the effectiveness of ILM 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 ILM 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 enhancements to the neoprobe GDS platform such as the 9mm wireless probe introduced at the Society of Surgical Oncology (SSO) 64th Annual Cancer Symposium held in March 2011.

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 Regents of the University of California through their UC, San Diego affiliate (UCSD). The UCSD license grants Neoprobe the commercialization rights to Lymphoseek for diagnostic imaging and intraoperative detection applications.

4

Lymphoseek (Tilmanocept) is a diagnostic imaging agent designed for radiolabeling and subsequent administration in radiodetection and visualization of the lymphatic system draining the region of injection for delineation of the lymphatic tissue. Lymphoseek is designed to accumulate in lymphatic tissue by specifically binding to mannose binding receptor (MBR; CD206) proteins that reside on the surface of resident dendritic cells and macrophages. Lymphoseek is a macromolecule consisting of multiple units of diethylene triamine pentaacetic acid (DTPA) and mannose, each synthetically attached to a 10 kDa dextran backbone. The mannose acts as a substrate for the receptor, and the DTPA serves as a chelating agent for labeling with Technetium Tc 99m.

The initial pre-clinical evaluations of Lymphoseek were completed in 2001. Since that time, Neoprobe, in cooperation with UCSD, has completed or initiated five Phase 1 clinical trials, one multi-center Phase 2 trial and three multi-center Phase 3 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 (intradermal injection, next day surgery)	1	31	Completed
Prostate	1	14	Closed
Colon	1	6	Closed
Breast or Melanoma	2	80	Completed
Breast or Melanoma	3	179	Completed
Breast or Melanoma	3	150	Node accrual target reached
Head and Neck Squamous Cell Carcinoma (“Sentinel”)	3	196*	Ongoing

*estimated number based upon interim analysis; actual number is dependent on statistical analysis at potential stoppage points

The Phase 1 studies to date have been supported in part through research grants from 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 meetings of the Society of Nuclear Medicine, the Society of Surgical Oncology and the World Sentinel Node Congress. The two Phase 1 studies in prostate and colon cancers were closed prior to planned target completion due in part to our determination that the planned product labeling for Lymphoseek, based on our dialogue with FDA, would be as a general lymphatic tissue tracing agent rather than as a disease-specific agent. The ongoing Phase 3 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.

5

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 additional 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, FDA raised a number of Chemistry, Manufacturing and Control (CMC) questions regarding the drug compound and 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 establish the commercial manufacturing process for filling and lyophilization of the drug product. 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. 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. The results of the Phase 2 study were published in the February 2011 online edition of the Annals of Surgical Oncology.

During 2008, we initiated patient enrollment in a Phase 3 clinical study in subjects with either breast cancer or melanoma (NEO3-05). In March 2009, we announced that this study had reached the accrual of 203 lymph nodes, the study’s primary accrual objective. The NEO3-05 Phase 3 clinical study was an open label trial of node-negative subjects with either breast cancer or melanoma. It was designed to evaluate the safety and the accuracy of Lymphoseek in identifying the lymph nodes draining from the subject’s tumor site. To demonstrate the accuracy of Lymphoseek, each subject consenting to participate in the study was injected in proximity to the tumor with Lymphoseek and one of the vital blue dyes that are commonly used in lymphatic mapping procedures. The primary efficacy objective of the study was to identify lymph nodes that contained the vital blue dye and to demonstrate a statistically acceptable concordance rate between the identification of lymph nodes with the vital blue dye and Lymphoseek. To be successful, the study needed to achieve a statistical p-value of at least 0.05. In addition, the secondary endpoint of the study was to pathologically examine lymph nodes identified by either the vital blue dyes or Lymphoseek to determine if cancer was present in the lymph nodes.

In June 2009, we initiated a Phase 3 clinical trial to be conducted in subjects with head and neck squamous cell carcinoma (NEO3-06). The NEO3-06 clinical study was designed to expand the potential labeling for Lymphoseek as a sentinel lymph node targeting agent after the initial marketing clearance for the product. Our discussions with FDA and the European Medicines Agency (EMA) have also suggested that the NEO3-06 clinical trial will further support the use of Lymphoseek in sentinel lymph node biopsy procedures. We believe the outcome of the trial will be beneficial to the marketing and commercial adoption of Lymphoseek in the U.S. and will support registration in the European Union (EU). Our plan remains to have approximately 20 participating institutions in the NEO3-06 clinical trial. Subject recruitment and enrollment is actively underway at a number of institutions and the trial protocol is currently under review at several other institutions. The accrual rate for this trial is slower than the accrual rate for the

NEO3-05 and NEO3-09 trials due in part to the incidence rate for head and neck cancers for subjects eligible to participate in this trial. We do not expect this trial to complete full accrual until sometime in 2012; however, there are opportunities to stop the trial at earlier points in the event we encounter subjects with disease-involved lymph nodes at a higher than historical expected rate.

In March 2010, Neoprobe met with FDA to review the clinical outcomes of NEO3-05. The meeting included a review of the efficacy and safety results of the NEO3-05 clinical study and Neoprobe's plans for the submission of a NDA for Lymphoseek based on the results of NEO3-05 and other previously completed clinical studies. During the meeting, Neoprobe provided FDA with the clinical results of the protocol-compliant clinical sites that participated in the NEO3-05 clinical study that contributed 136 intent-to-treat subjects who provided 215 lymph nodes containing the vital blue dye. 210 of the vital blue dye positive lymph nodes contained Lymphoseek for an overall concordance rate of 98%, achieving a very high level of statistical correlation (p-value = 0.0001) for the primary endpoint of the clinical study. Prior to the meeting, FDA requested that Neoprobe conduct a "reverse concordance" assessment of the clinical study where Lymphoseek might identify lymph nodes missed by the vital blue dyes. This assessment showed that Lymphoseek was able to identify 85 additional lymph nodes that did not contain the vital blue dye, and 18% of these nodes were found by pathology to contain cancer. There were no significant reported safety events related to Lymphoseek. FDA indicated that the clinical data from the NEO3-05 clinical study and other completed clinical evaluations of Lymphoseek would be supportive of a NDA submission for Lymphoseek. FDA also encouraged Neoprobe to request a series of pre-NDA meetings to review the non-clinical and chemistry, manufacturing and control (CMC) components of the NDA prior to its formal submission. Neoprobe completed successful non-clinical and CMC pre-NDA reviews with FDA during the second quarter of 2010.

As a result of the March 2010 meeting, we moved forward with a plan to file the NDA for Lymphoseek later in 2010. A key part of the plan, however, was to ensure that the patient population in the safety database that would be considered in the approval of Lymphoseek would be adequate to meet the expectations of FDA. As such, in July 2010, Neoprobe initiated enrollment in another Phase 3 clinical evaluation of Lymphoseek in subjects with either breast cancer or melanoma (NEO3-09) which we expected would accrue patients, primarily for purposes of augmenting the safety population and to support expanded product labeling claims. Based on guidance received in the March 2010 meeting, we planned to file data related to the NEO3-09 trial as part of a planned major amendment to the primary NDA.

In October 2010, Neoprobe met with FDA for a pre-NDA assessment for Lymphoseek. As a result of the pre-NDA assessment, FDA requested that data from both the completed NEO3-05 study and the NEO3-09 study currently in progress be included in the Company's primary NDA for Lymphoseek rather than submitting the NEO3-09 study safety data as a planned major amendment to the ongoing NDA review, as initially intended. The pre-NDA assessment resulted in no modification to the NEO3-09 trial design or endpoints or to any of the other previously agreed-to clinical or regulatory components of the Lymphoseek NDA. As such, NEO3-09 will now be one of two adequate and well-controlled trials included in the primary NDA submission for a first-cycle review.

In February 2011, we announced that we had enrolled an adequate number of subjects to enable us to meet the lymph node accrual goal for the NEO3-09 clinical trial. Preliminary top-line data are expected to be announced in the second quarter of 2011. In addition, the results of the NEO3-09 clinical study may support the inclusion of enhanced product claims for Lymphoseek in the primary NDA submission.

The Lymphoseek NDA submission will be based on the clinical results of the Phase 3 clinical studies NEO3-05 and NEO3-09, and other already completed clinical evaluations of Lymphoseek. The request for the total data package from two Phase 3 clinical trials is consistent with FDA's ongoing initiative to push for more complete primary submissions and to limit major amendments made to NDAs. This ongoing initiative to shorten drug review cycle times was re-emphasized by FDA's Office of New Drug Development in late 2009 and enables more successful first-cycle reviews which ultimately shortens overall drug approval timelines. We believe inclusion of the NEO3-09 study data in the primary NDA submission may support stronger product labeling as an outcome of a first-cycle review of the Lymphoseek NDA and may also positively impact market adoption.

We plan to use the safety and efficacy results from the NEO3-06 Phase 3 clinical evaluations of Lymphoseek, which will include sites in the EU, to support the drug registration application process in the EU through the centralized drug authority EMA as well as to amend the filing in the U.S. for expanded product labeling. Neoprobe expects to submit the NDA for Lymphoseek during the first half of 2011. Depending on the timing and the outcome of the FDA regulatory review cycle, we believe that Lymphoseek could be commercialized in early 2012. 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 with proprietary radiolabeled cancer-specific targeting agents to provide surgeons with real-time information to locate tumor deposits generally 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 radiopharmaceutical agents used in the RIGS process are monoclonal antibodies that are specific for cancer markers, or antigens, 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 is an intraoperative biologic targeting agent consisting of a radiolabeled murine monoclonal antibody (CC49 MAb, Minretumomab). Various potential radioisotopes can be used as the radiolabel. 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.

The RIGS system was conceived to be a diagnostic aid in the intraoperative detection of clinically occult disease in patients with colon or rectal cancer. RIGScan CR is intended to be used in conjunction with other diagnostic methods for the detection of the extent and location of occult tumor and tumor metastases 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 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 EMA 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.

8

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 EMA. Both FDA and EMA 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 enhancing patient outcomes 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 EMA 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 guidance and pathways for approval that existed at that time, we determined that we did not have sufficient financial resources to conduct the additional studies requested.

In 2004, we obtained access to survival analyses of patients treated with RIGScan CR which have been prepared by third parties, indicating that RIGScan status was correlated with patient survival trends and 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. These data and its possible significance were unknown at the time of the BLA review given the limited maturity of the follow-up experience. The data include 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. Based primarily on this survival-related 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 these 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 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. 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.

Our statistical analyses following the 2004 meeting with FDA indicated that a potential sample size of 2,400 to 2,800 patients would be required in clinical studies to get RIGScan CR registered, which proved cost prohibitive to us and our potential development partners in evaluating continued development for RIGScan CR. However, during 2008 we developed a protocol design which we believe could support our desired clinical endpoints but in a much smaller patient population. We held a pre-submission meeting with EMA and received positive feedback to the clinical trial design which involved approximately 400 patients. EMA subsequently indicated preliminary concurrence with a plan to harmonize the U.S. and EU regulatory pathways.

Our desire has been, and continues to be, to develop a clinical development plan which is harmonized between the U.S. and the EU in order to fully engage potential development partners. To that end, during December 2009 we submitted an IND amendment to FDA which included the design of a proposed Phase 3 clinical trial of RIGScan CR. Since filing the IND amendment, we have determined that due to differences in the current manufacturing process from the process used in the 1990's, a further amendment to the IND should be filed addressing the differences. In addition, in October 2010, we filed a response letter to FDA related to the Agency's complete response letter to the open BLA from 1997. The review responsibility for the RIGS BLA was recently transferred from CBER to the Division of Medical Imaging Products in CDER at FDA. The submission of the BLA response letter was the first of several near-term activities that Neoprobe intends to complete with FDA to reactivate the development of the RIGS technology. We have since filed a new IND request for the biologic component of the RIGS technology and held a pre-IND meeting with FDA to discuss the clinical development and regulatory plans for RIGScan.

The focus of Neoprobe's February 2011 pre-IND meeting with FDA was to first define the basic CMC requirements needed to resume clinical development efforts on RIGScan. FDA reviewed Neoprobe's comprehensive pre-IND package, including key aspects of the clinical development and drug development plans, and provided clear direction to the Company on its clinical and manufacturing activities going forward. As an outcome of the pre-IND meeting, we have clarified the path to reinitiate RIGScan development and the requirements for resuming development activities and moving toward clinical trials, FDA's guidance has provided direction to enhance our manufacturing platform, including process improvements to increase manufacturing efficiency and the quality of the underlying biologic antibody. We can now begin to implement our manufacturing plans through 2011 as a first step to recommencing clinical study of the technology in 2012 and beyond.

It should also be noted that the RIGScan biologic drug has not been produced for several years. We have successfully completed the initial steps in re-characterizing the drug cell line and believe, based on work done to date, that the cell line is still viable. We plan to submit these data to EMA and FDA for their evaluation in connection with preparations to restart pivotal clinical trials. During the third quarter of 2009, we announced that we had executed a Biopharmaceutical Development and Supply Agreement with Laureate Biopharmaceutical Services, Inc. (Laureate Biopharma). This agreement will support the initial evaluation of the viability of the CC49 master working cell bank as well as the initial steps in re-validating the commercial production process for the biologic agent used in RIGScan. Laureate Biopharma has made progress in the re-validation of the manufacturing process and has completed preliminary biologic characterization activities. They are expected to provide Neoprobe with cGMP-produced material to support non-clinical and clinical evaluation within the next few months. Our development plans for RIGScan include the consideration of alternative radiolabeling processes. Depending on the outcome of our evaluation, we will need to establish radiolabeling capabilities for the CC49 antibody in order to meet the regulatory needs for the RIGScan product. We have already begun discussions with parties capable of supporting such activities.

We believe it will likely be necessary and beneficial for us to identify a development partner to prepare for the pivotal clinical testing that will be necessary to gain marketing clearance for RIGScan. Such a partner may or may not be involved in funding future RIGS development. In the past, we have engaged in discussions with various parties regarding potential partnerships. We believe the recently clarified regulatory pathway with FDA is very valuable, and we believe re-approaching the EMA through the scientific advice process will be helpful in clarifying the regulatory

pathway in the EU and will be helpful for us and our potential partners in assessing the full potential for RIGScan. 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 EMA will clear our RIGS products for marketing or that any such products will be successfully introduced or achieve market acceptance. See Risk Factors.

Activated Cellular Therapy

Through various research collaborations, we performed early-stage research during the late 1990's 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 expanded, 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-derived 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. Cira Bio has attempted over the past few years 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; however, this option expired in 2008. The prospects for the ACT technology were buoyed during the fourth quarter of 2009 as a result of the publication of the discovery of a retrovirus linked to chronic fatigue syndrome, an autoimmune dysfunction the treatment of which showed promise during the early clinical trials for ACT. Scientists are continuing to evaluate the data regarding the linkage. Should the link to the retrovirus be further substantiated, the development prospects for ACT will likely improve. We do not know if our assessment of the technology's prospects will ultimately yield positive results or 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. Espicom Business Intelligence estimated in 2010 an annual medical device market of $95 billion in the U.S. and $230 billion internationally.

Cancer Market Overview

Cancer is the second leading cause of death in the U.S. and Western Europe and was estimated by the ACS to be responsible for over 569,000 deaths annually in 2010 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 2010 at $263.8 billion: $102.8 billion for direct medical costs, $20.9 billion for indirect morbidity, and $140.1 billion for indirect mortality. Our line of gamma detection systems is currently used primarily in the application of ILM in breast cancer and melanoma which, according to the ACS, have been estimated to account for 14% and 4%, respectively, of new cancer cases which occurred in the U.S. in 2010.

The NIH has estimated that 1.4 million new cases of invasive breast cancer are expected to occur annually among women worldwide. 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 few years, generally increases with age, rising from about 120 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 207,000 new cases of invasive breast cancer are expected to be diagnosed and approximately 40,000 women are estimated to have died from the disease during 2010 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 may 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 $450 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. See Risk Factors.

The ACS has also estimated that nearly 143,000 new incidences of colon and rectal cancers were expected to occur in the U.S. in 2010. Based on an assumed recurrence rate of 40%, this would translate into total potential surgical procedures of approximately 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 $3 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. See Risk Factors.

12

Marketing and Distribution

Gamma Detection Devices

We began marketing the neo2000 gamma detection system in October 1998. From October 1999 through July 2010, our gamma detection systems have been marketed and distributed throughout most of the world through Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company. 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. In July 2010, EES sold its breast care franchise to Devicor Medical Products, LLC (Devicor). As a part of the acquisition, Devicor took on EES' sales and marketing resources in the U.S. and certain rest-of-world markets. In connection with their acquisition of EES' breast care franchise, Devicor assumed all of EES' rights and responsibilities related to the sales, marketing and distribution of our gamma detection products. Under this agreement, we manufacture and sell our gamma detection medical devices on an exclusive basis to Devicor. Devicor 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 Devicor 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. 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 Devicor 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. 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 significant share of the revenue from each patient dose of Lymphoseek sold. In addition, Neoprobe will receive up to $3 million in payments upon the achievement of certain sales milestones by Cardinal Health. We have had preliminary discussions with potential marketing and distribution partners in the EU and other major world markets; however, we do not currently have collaborative agreements covering Lymphoseek in areas of the world other than the U.S. 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 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 further clinical testing that will be necessary to gain marketing clearance for RIGScan CR. We are aware of potential development partners who have previously indicated an interest in entering into a development relationship and expect to have ongoing discussions with such parties in the coming months; however, we do not expect to enter into any definitive partnership at least until we have further advanced the clinical testing for RIGScan CR. 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.

Manufacturing

Gamma Detection Devices

As part of our virtual business model, 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 Microelectronics, a division of Endicott Interconnect Technologies, Inc. (eV), Redlen Technologies (Redlen) and Nortech Systems, Inc. (Nortech). We also purchase certain accessories for our line of gamma detection systems from other qualified manufacturers.

We purchase certain solid-state crystals used in the manufacture of our proprietary line of hand-held gamma detection probes from eV and Redlen. We do not currently have a supply agreement with either eV or Redlen, however we currently purchase from both under extended blanket purchase orders. The number of potential suppliers of such solid-state crystals is limited. However, we believe our relationships with eV and Redlen mitigate the risk of prolonged interruption of supply of crystals that could negatively impact the availability of our probe gamma detection device products, which would accordingly adversely affect our operating results.

In February 2004, we executed a Product Supply Agreement with TriVirix International, Inc. (TriVirix) for the manufacture and/or final assembly of our gamma detection products, including probes and control units. This agreement was assigned to Nortech in connection with Nortech’s acquisition of TriVirix during 2010. The original term of this agreement expired in February 2007 but has been extended under the automatic renewal terms of the agreement through February 2012. The agreement will continue to be automatically extended for successive one-year periods unless six months notice is provided by either party.

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 in our Phase 3 work completed to date, and is expected to be used in the ongoing Phase 3 clinical work. Reliable has produced the active pharmaceutical ingredient (API) and OSO Bio has performed final product manufacturing including final drug formulation, lyophilization (i.e., freeze-drying) and packaging processes. Once packaged, the vialed drug can then be shipped to a hospital or regional commercial radiopharmacy where it can be made radioactive (i.e., radiolabeled) with Technetium 99m (Tc99m) to become the final form of 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 EMA. Both Reliable and OSO Bio are registered manufacturers with FDA and/or EMA. In November 2009, we completed a Manufacture and Supply Agreement with Reliable for the manufacture of the bulk API material with an initial term of 10 years. At this point, drug product produced by OSO Bio has been manufactured under clinical development agreements. A commercial supply agreement is being negotiated with OSO Bio. We cannot assure you that we will be successful in reaching an agreement with OSO Bio on terms satisfactory to us, or at all. We also 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 are 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.

During the third quarter of 2009, we announced that we had executed a Biopharmaceutical Development and Supply Agreement with Laureate Biopharma. This agreement will support the initial evaluation of the viability of the CC49 master and working cell banks as well as the initial steps in re-validating the commercial production process for the biologic agent used in RIGScan CR. 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. We have also begun discussions with parties capable of supporting such activities.

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. 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 Devicor's (previously 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. 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 that would be used intraoperatively in the colorectal cancer application that RIGScan 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.

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. In addition, many surgeons use vital blue dyes to assist in the visual identification of the draining lymphatic tissue. 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 lymph node targeting agent.

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

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 has also been issued in Japan. We have filed additional patent applications in the United States related to the manufacturing processes for Lymphoseek.

16

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. Additionally, statutory exclusivity exists for biologics upon approval in the U.S. for 12 years. In the EU, 10 years of data exclusivity are provided for.

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 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.

Gamma Detection Radiopharmaceuticals

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 $9.2 million and $5.0 million on research and development activities in the years ended December 31, 2010 and 2009, respectively.

Employees

As of March 11, 2011, we had 32 full-time and 10 part-time employees. We consider our relations with our employees to be good.

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 prospectus, including our financial statements and the related notes, before you decide to buy our common stock. Our most significant risks and uncertainties are described below; however, they are not the only risks we face. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading of our common stock could decline, and you may lose all or part of your investment therein.

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 radiopharmaceutical product candidates have 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/or
- 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.

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 2009, we successfully completed a Phase 3 clinical trial in subjects with breast cancer or melanoma for our most advanced radiopharmaceutical product candidate, Lymphoseek. We are in the process of completing a second Phase 3 trial for this product also in subjects with breast cancer or melanoma and a third Phase 3 clinical trial in subjects with head and neck squamous cell carcinoma. In late 2008, we obtained approval from EMA for a Phase 3 clinical protocol for our next radiopharmaceutical candidate, RIGScan, and are preparing to approach FDA to obtain similar clearance. Historically, the results from preclinical testing and early clinical trials have often not been generally 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 EMA 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
- commercialize existing and future product candidates.

We have an agreement in place 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 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 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 $251 million as of December 31, 2010. Although we were profitable in 2000 and 2001, we incurred substantial losses in the years prior to that, and again in subsequent years. The accumulated 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, sentinel lymph node biopsy (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, we believe 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.

Our radiopharmaceutical product candidates, Lymphoseek and RIGScan, 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 rely on third parties for the worldwide marketing and distribution of our gamma detection devices, who may not be successful in selling our products.

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

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 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. 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 medical device 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. 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 Devicor 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. We are in the process of finalizing supply contracts with third-party manufacturers for our Lymphoseek product. However, 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 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 and adversely affect our business.

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. On March 23, 2010, health reform legislation was approved by Congress and has been signed into law. The reform legislation provides that most individuals must have health insurance, will establish new regulations on health plans, create insurance pooling mechanisms and other expanded public health care measures, and impose new taxes on sales of medical devices and pharmaceuticals. Since this legislation is recently enacted, and since significant portions may be amended or repealed, we cannot predict the effect, if any, that it will have on our business, but this legislation and similar federal and state initiatives may have the effect of lowering reimbursements for our products, reducing medical procedure volumes, increasing our taxes and otherwise adversely affect our business, possibly materially.

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

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

We expect to continue to devote significant capital resources to fund research and development and to maintain existing and secure new manufacturing capacity. In order to support the initiatives envisioned in our business plan, we may need to raise additional funds through the sale of assets, public or private debt or equity financing, collaborative relationships or other arrangements. Our ability to raise additional financing depends on many factors beyond our control, including the state of capital markets, the market price of our common stock and the development or prospects for development of competitive technology by others. 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. Depending on market conditions and/or changes in our business plans, we may attempt to raise additional capital during 2011. The potential volatility in market conditions 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.

The sale of the shares of common stock acquired in private placements could 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, as more fully described in Item 7 of this Report under the caption "Liquidity and Capital Resources." 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.

We have no way of knowing whether or when the investors 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.

25

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.

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.

26

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

Our business has experienced a number of successes and faced several challenges in recent 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. 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 biotechnology 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 failure to maintain continued compliance with the listing requirements of the NYSE Amex Equities exchange could result in the delisting of our common stock.

Our common stock was recently listed on the NYSE Amex Equities exchange (Exchange). The rules of the Exchange provide that shares be delisted from trading in the event the financial condition and/or operating results of the Company appear to be unsatisfactory, the extent of public distribution or the aggregate market value of the common stock has become so reduced as to make further dealings on the Exchange inadvisable, the Company has sold or otherwise disposed of its principal operating assets, or has ceased to be an operating company, or the Company has failed to comply with its listing agreements with the Exchange. There can be no assurance that the Company will continue to meet the requirements necessary to maintain the listing of its common stock on the Exchange, and in the event of a delisting, the market for our common stock could become significantly less liquid, which would likely adversely affect its value.

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 $1.42 per share and as high as $4.71 per share during the 12-month period ended March 11, 2011. 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.

Historically, the trading volume for our common stock has been relatively limited. The average daily trading volume for our common stock on the OTC Bulletin Board for the 12-month period ended January 31, 2011 was approximately 194,000 shares. Following the listing of our common stock on the Exchange on February 10, 2011, we expect the

market in our common stock to be more active, although we cannot assure that this will occur or will be consistently maintained in the future.

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 on common stock 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 15,000 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 through January 31, 2013, at a monthly base rent of approximately $11,600 during 2011. We must also pay a pro-rata portion of the operating expenses and real estate taxes of the building. We believe these facilities are in good condition, but that we may need to expand our 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. (Removed and Reserved)

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 NYSE Amex stock exchange under the trading symbol NEOP. Prior to being listed on the NYSE Amex beginning February 10, 2011, our common stock was traded on the OTC Bulletin Board under the trading symbol NEOP.OB. The prices set forth below reflect the quarterly high, low and closing sales prices for shares of our common stock during the last two fiscal years as reported by Reuters Limited. These quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions.

	High	Low	Close
Fiscal Year 2010:			
First Quarter	$ 2.30	$ 1.15	$ 1.64
Second Quarter	2.00	1.50	1.80
Third Quarter	2.15	1.66	1.88
Fourth Quarter	2.32	1.50	2.06
Fiscal Year 2009:			
First Quarter	$ 0.80	$ 0.42	$ 0.54
Second Quarter	1.20	0.35	0.95
Third Quarter	1.48	0.91	1.40
Fourth Quarter	1.40	0.95	1.22

As of March 11, 2011, we had approximately 740 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.

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 oncology products that enhance patient care and improve patient treatment. We currently market a line of medical devices, our neoprobe® GDS gamma detection systems. In addition to our medical device products, we have two

radiopharmaceutical products, Lymphoseek® and RIGScanTM 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 Overview section contains a number of forward-looking statements, all of which are based on current expectations. Actual results may differ materially. Our financial performance is highly dependent on our ability to continue to generate income and cash flow from our 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 believe that the future prospects for Neoprobe continue to improve as we make progress in all of our key growth and development areas, especially related to our Lymphoseek initiative. Our gamma detection device line continues to provide a solid revenue base producing cash flow to cover our public company overhead and contribute to funding our research and development efforts. We expect our overall research and development expenditures to rise in 2011 over 2010 as we have expanded our clinical and regulatory staffing to support the commercialization of Lymphoseek and further development of RIGScan and as we take steps to expand our product pipeline. The level to which the expenditures rise will depend on the extent to which we are able to execute on each of these strategic initiatives, but we are confident we will have the resources necessary to execute on these initiatives. We expect to continue to incur modest development expenses to support our device product lines as well as we work to expand our product offerings in the gamma detection device arena. Our primary development efforts over the last few years have been focused on our oncology drug development initiatives: Lymphoseek and RIGScan. We continue to make progress with both initiatives; however, neither Lymphoseek nor RIGScan is anticipated to generate any significant revenue for us during 2011.

In August 2009, the Company's Board of Directors decided to discontinue the operations of Cardiosonix and to attempt to sell our Cardiosonix subsidiary. This decision was based on the determination that the blood flow measurement device segment was no longer considered a strategic initiative of the Company, due in large part to positive events in our other device product and drug development initiatives. To this point, we have not had significant interest expressed in Cardiosonix, and as such, we continue to wind down our activities in this area. Until a final shutdown of operations or a sale of the business unit is completed, we expect to continue to generate modest revenues and incur minimal expenses related to our blood flow measurement device business.

Our efforts in 2010 resulted in the following milestone achievements:

- Completed a successful meeting with the United States Food and Drug Administration (FDA) to review the Phase 3 (NEO3-05) clinical study results and development plan discussion to support a New Drug Application (NDA) submission for Lymphoseek as a lymphatic tissue tracing agent;
- Completed a successful pre-NDA dialogue with FDA on Lymphoseek pre-clinical data;
- Completed a successful pre-NDA dialogue with FDA on Lymphoseek chemistry, manufacturing and control data;
- Initiated a third Lymphoseek Phase 3 clinical study in subjects with breast cancer or melanoma (NEO3-09) to support the NDA filing with the potential to expand Lymphoseek's product labeling;
- Completed a pre-NDA meeting for Lymphoseek clarifying the regulatory pathway for Lymphoseek approval;
- Elected two new directors to Neoprobe's Board, bringing significant drug industry and corporate development expertise to the Company's leadership;
- Completed transactions that converted all of the Company's outstanding debt to equity;
- Received notice of grant awards of over $1.2 million to support future Lymphoseek development through non-dilutive funding;

- Filed a shelf registration on Form S-3 to allow the Company to raise capital as necessary through the sale of up to $20 million in a primary offering of securities to provide us with additional financial planning flexibility and to support the diversification of our share ownership to new institutions;
- Completed an offering and sale of common stock and warrants under the shelf registration statement resulting in approximately $5.5 million in net proceeds to the Company and the potential for an additional $7.0 million in proceeds from the cash-only exercise of the warrants included in the placement;
- Completed preliminary RIGS® development activities including transfer of the biologic license application (BLA) from the Center for Biologics Evaluation and Research (CBER) to the Division of Medical Imaging Products in the Center for Drug Evaluation and Research (CDER) at FDA and preparation of an investigational new drug (IND) request for the biologic product; and
- Filed a complete response to the open BLA for RIGScan.

Our Outlook for our Drug and Therapeutic Initiatives

Our operating expenses during 2010 were focused primarily on support of Lymphoseek product development, and to a lesser extent, on efforts to restart active development of RIGScan. We expect our drug-related development expenses to increase in 2011 as we complete the NEO3-09 clinical trial, prepare and file the NDA for Lymphoseek with FDA, and support the other drug stability and production validation activities related to supporting the potential marketing registration of Lymphoseek in the U.S. and other major markets. In addition, following the recent meeting with FDA regarding the development and regulatory pathway for RIGScan, we expect to incur significant expenses related to pre-clinical and manufacturing activities necessary to prepare to re-enter clinical trials with RIGScan in 2012. To the extent we are successful in identifying and securing additional product candidates to augment our product development pipeline, we may incur additional expenses related to furthering the development of such products.

Our Outlook for our Gamma Detection Device Business

We believe our core gamma detection device business line will continue to achieve positive results in 2011. 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, including a higher-energy gamma detection probe which was launched in mid- 2009 and a 9mm probe introduced at the recent Society of Surgical Oncology meeting in March 2011.

Our gamma detection devices are distributed in most global markets by Devicor Medical Products, Inc. (Devicor). Prior to July 2010, our gamma detection device products were marketed through a distribution arrangement with Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company. In July 2010, Devicor acquired EES' breast care business, including an assignment of the distribution agreement with Neoprobe. Under the terms of our distribution agreement with Devicor, the transfer prices we receive on product sales to Devicor 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. 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 in 2011, 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 Devicor that may erode some or all of the premium we received in prior years in excess of the floor price. Overall, we expect revenues from our gamma detection devices to result in a net profit in 2011 for that line of business, excluding general and administrative costs, interest and other financing-related charges; however, as the market continues to approach saturation into current applications, we do not expect significant growth in the market for gamma detection devices until after the impact of Lymphoseek is felt in the application of SLNB beyond breast cancer and melanoma.

Our overall operating results for 2011 will also be greatly affected by the increased level of development activity we continue to conduct to support our radiopharmaceutical products. Primarily as a result of the significant development costs we expect to incur related to the continued clinical development of Lymphoseek and RIGScan, we do not expect to achieve overall operating profitability during 2011. 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. See Risk Factors.

Results of Operations

Revenue for 2010 increased to $10.7 million from $9.5 million in the prior year. The increase was primarily due to recognition of $617,000 in revenue from grants awarded during 2010 as well as increased unit sales and unit prices of our control units, increased unit sales of our wireless probes, and increased unit prices of our 14mm corded probes, offset by decreased unit sales of our high-energy and 14mm corded probes and decreased unit sales of our wireless probes. Gross margins for 2010 increased to 70% as compared to 67% in 2009. The increase in gross margins was primarily due to recognition of grant revenue and overall increased sales prices of our gamma detection devices.

In June 2010, Neoprobe was notified that Ohio's Third Frontier Commission voted to award a grant of $1 million to fund ongoing development of the Company's Lymphoseek initiative. The grant is being used to accelerate the application of Lymphoseek in head and neck cancer treatment and involves a collaboration of several Ohio-based companies as well as leading cancer centers in the US. Neoprobe and its collaborators will be required to contribute an additional $1.1 million in matching funds over the course of the project. We recognized approximately $358,000 in Ohio Third Frontier grant revenue during 2010, and expect to recognize the remaining $642,000 as revenue during 2011 and 2012. In October 2010, Neoprobe was awarded a grant of approximately $244,000 under the Qualifying Therapeutic Discovery Project (QTDP) program established under Section 48D of the Internal Revenue Code. The QTDP grant was a reimbursement of previous expenditures and there is no requirement for future matching funds from Neoprobe. We recognized the entire $244,000 of QTDP grant revenue in the fourth quarter of 2010. During the fourth quarter of 2010, Neoprobe received and recognized an additional $15,000 of miscellaneous grant revenue.

Net Sales and Margins. Net sales, comprised primarily of sales of our gamma detection systems, increased $565,000, or 6%, to $10.0 million during 2010 from $9.4 million in 2009. Gross margins on net sales increased slightly to 68% of net sales for 2010 compared to 67% of net sales for 2009.

The increase in net sales was the result of increased gamma detection device sales of $492,000, increased gamma detection device extended service contract revenue of $54,000, and increased gamma detection device non-warranty service revenue of $19,000. Of the $492,000 increase in gamma detection device sales, approximately $447,000 was attributable to increased net sales volumes and $45,000 was attributable to increased net sales prices. The price at which we sell our gamma detection device products to Devicor is based on a percentage of the global ASP received by Devicor on sales of Neoprobe products to end customers, subject to a minimum floor price. The slight increase in gross margins was primarily due to increased prices on certain of our gamma detection device products coupled with decreased costs of our wireless probes.

Research and Development Expenses. Research and development expenses increased $4.2 million, or 86%, to $9.2 million during 2010 from $5.0 million in 2009. The increase was primarily due to higher Lymphoseek development expenses related to conducting the Phase 3 clinical trials and preparing to file the NDA, higher RIGS development expenses related to product and process development, and higher compensation costs due to incentive-based compensation and increased headcount required to conduct our drug development activities. Research and development expenses in 2010 included approximately (i) $8.7 million in drug and therapy product development costs and (ii) $568,000 in gamma detection device development costs. This compares to expenses of $3.9 million and $1.1 million, respectively, in these segment categories in 2009. The changes in drug and therapy product development costs were primarily due to increased process development costs of $1.5 million, clinical activity costs of $962,000, regulatory consulting costs of $303,000, and market analysis costs of $217,000 related to Lymphoseek; increased compensation costs of $555,000 related to increased headcount and incentive-based compensation; and increased process development costs of $544,000, regulatory consulting costs of $118,000, market analysis costs of $108,000, and license fees of $62,000 related to RIGScan CR. The changes in gamma detection device development costs were primarily due to lower development costs related to our new high-energy detection probe, which was launched in 2009, of $128,000 and lower net development costs related to various other product improvements of $32,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $1.4 million, or 41%, to $4.6 million during 2010 from $3.2 million in 2009. The increase was primarily due to compensation costs of $502,000 related to increased headcount and incentive-based compensation, increased financial advisory fees of $304,000, increased investor relations fees of $285,000 related to re-listing the Company's stock on a major exchange, increased professional services of $96,000, and the audit of our internal control over financial reporting of $70,000.

Other Income (Expense). Other expense, net increased $7.7 million to $43.6 million in 2010 from $35.9 million in 2009. During 2010, we recorded a non-cash loss on the extinguishment of debt of $41.7 million related to the exchange of our outstanding convertible debt for convertible preferred stock. During 2009, we recorded a $16.2 million non-cash loss on extinguishment of debt related to changes in the terms of our convertible debt, convertible preferred stock and the related warrants to purchase our common stock. During 2010 and 2009, we recorded charges of $1.3 million and $18.1 million, respectively, related to the increase in the fair value of our derivative liabilities resulting from the requirement to mark our derivative liabilities to market. Interest expense, primarily related to the convertible debt agreements we completed in December 2007 and April 2008 and extinguished in June 2010, decreased $978,000 to $555,000 in 2010 from $1.5 million in 2009. Of this interest expense, $16,000 and $428,000 in 2010 and 2009, respectively, were non-cash in nature related to the amortization of debt issuance costs and debt discounts resulting from the warrants and conversion features of the convertible debt. An additional $403,000 and $917,000 of interest expense in 2010 and 2009, respectively, was non-cash in nature due to the payment or accrual of interest on our convertible debt with shares of our common stock.

Discontinued Operations. During the third quarter of 2009, we made the decision to discontinue operations of the blood flow measurement device segment of our business as the segment was no longer considered a strategic initiative of the Company. This determination was based in large part on positive events in our other development initiatives. As a result, we recorded an impairment loss for discontinued operations of $1.7 million for the year ended December 31, 2009. Total revenues from discontinued operations were $57,000 and $129,000 in 2010 and 2009, respectively. The loss from discontinued operations was $87,000 and $176,000 for 2010 and 2009, respectively.

Liquidity and Capital Resources

Cash balances increased to $6.4 million at December 31, 2010 from $5.6 million at December 31, 2009. The net increase was primarily due to cash received for the issuance of common stock, offset by cash used to fund our operations, mainly for research and development activities.

Operating Activities. Cash used in operations increased $3.7 million to $5.2 million during 2010 compared to $1.5 million during 2009.

Accounts receivable increased to $2.0 million at December 31, 2010 from $1.3 million at December 31, 2009. The increase was primarily a result of fluctuations in timing of purchases and payments by our primary customers. We expect overall receivable levels will continue to fluctuate during 2011 depending on the timing of purchases and payments by our customers.

Inventory levels increased to $1.5 million at December 31, 2010 from $1.1 million at December 31, 2009. Gamma detection device materials and finished goods inventory levels increased as we have increased our product safety stock levels to ensure efficient and uninterrupted supply of our products to our distribution partners. During 2010, we capitalized $741,000 of pharmaceutical materials related to our Lymphoseek product; however, also during 2010, we expensed $634,000 of previously capitalized pharmaceutical materials to research and development as they were no longer considered to be usable in the production of future saleable drug product inventory. We expect inventory levels to increase over 2011 as we produce additional drug inventory in anticipation of the Lymphoseek product launch.

Accounts payable increased to $1.5 million at December 31, 2010 from $764,000 at December 31, 2009. The increase was primarily due to increased manufacturing, regulatory, and clinical activities related to advancing our Lymphoseek and RIGScan initiatives. Our payables balances will continue to fluctuate but will likely increase overall as we increase our level of development activity related to RIGScan.

Investing Activities. Investing activities used $399,000 of cash during 2010 compared to providing $327,000 during 2009. Available-for-sale securities of $494,000 matured during 2009. Capital expenditures of $367,000 during 2010 were primarily for equipment to be used in the production of Lymphoseek, office furniture, software, and computers. Capital expenditures of $96,000 during 2009 were primarily for computers, production and laboratory equipment, and software. We do not expect to incur significant additional costs for Lymphoseek production equipment. As such, we expect our overall capital expenditures for 2011 will be lower than 2010. Payments for patent and trademark costs decreased to $32,000 during 2010 compared to $71,000 during 2009.

Financing Activities. Financing activities provided $6.3 million of cash during 2010 compared to $3.2 million provided during 2009. The $6.3 million provided by financing activities in 2010 consisted primarily of proceeds from the issuance of common stock of $7.1 million, offset by payments of stock offering costs of $611,000, payments of preferred stock dividends of $111,000, payments of capital leases of $12,000, and payments of notes payable of $9,000. The $3.2 million provided by financing activities in 2009 consisted primarily of proceeds from the issuance of common stock of $3.6 million, offset by payments of stock offering costs of $238,000, payments of notes payable of $138,000, payments of debt issuance costs of $20,000, and payments of capital leases of $9,000. We do not rely to any material extent on short-term borrowings for working capital or to fund our operations.

In December 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (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. Upon execution of the agreement, we issued to Fusion Capital 720,000 shares of our common stock as a commitment fee. Through November 2008, we sold to Fusion Capital under the agreement 7,568,671 shares for proceeds of $1.9 million. 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 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. As consideration for Fusion Capital's agreement to enter into the amendment, we issued Fusion Capital an additional 360,000 shares. Also, we agreed to issue to Fusion Capital an additional 486,000 shares of our common stock as a commitment fee pro rata as we sold the first $4.1 million of our common stock under the amended agreement. In March 2010, we sold to Fusion Capital under the amended agreement 540,541 shares for proceeds of

$1.0 million and issued an additional 120,000 shares of our common stock to Fusion Capital as an additional commitment fee related to the sale. The agreement with Fusion Capital expired as planned on March 1, 2011, and as a result, Fusion Capital may liquidate any commitment fee shares issued to it during the term of the 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 Bupp Note bore interest at 10% per annum, had an original term of one year and was repayable in whole or in part with no penalty. The note was convertible, at the option of the Bupp Investors, into shares of our common stock at a price of $0.31 per share. 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.

In December 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, $3.5 million of which was convertible into shares of our common stock at the conversion price of $0.26 per share, 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.

In connection with the SPA, Montaur requested that the term of the $1.0 million Bupp Note be extended approximately 42 months or until at least one day following the maturity date of the Series A Note. 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 additional 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.

In April 2008, following receipt by the Company of clearance from the United States Food and Drug Administration 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, which was convertible into shares of our common stock at the conversion price of $0.36 per share, 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.

In December 2008, after we obtained 135 vital blue dye lymph nodes from patients who had completed the injection of the drug and surgery 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 Series A 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 (hereinafter referred to collectively with the Series W warrant and Series X warrant as the Montaur Warrants), for an aggregate purchase price of $3,000,000. The "Liquidation Preference Amount" for the Series A Preferred Stock was $1,000 and the "Conversion Price" of the Series A Preferred Stock was set at $0.50 on the date of issuance, thereby making the shares of Series A Preferred Stock convertible into an aggregate 6,000,000 shares of our common stock, subject to adjustment as described in the Certificate of Designations.

In July 2009, we entered into a Securities Amendment and Exchange Agreement with Montaur, pursuant to which Montaur agreed to the amendment and restatement of the terms of the Montaur Notes, the Series A Preferred Stock, and the Montaur Warrants. The Series A Note was amended to grant Montaur conversion rights with respect to the $3.5 million portion of the Series A Note that was previously not convertible. The newly convertible portion of the Series A Note was convertible into 3,600,000 shares of our common stock at $0.9722 per share. The amendments also eliminated certain price reset features of the Montaur Notes, the Series A Preferred Stock and the Montaur Warrants that had created significant non-cash derivative liabilities on the Company's balance sheet. In conjunction with this transaction, we issued Montaur a Series AA Warrant to purchase 2.4 million shares of our common stock at

an exercise price of $0.97 per share, expiring in July 2014. The change in terms of the Montaur Notes, the Series A Preferred Stock and the Montaur Warrants were treated as an extinguishment of debt for accounting purposes. Following the extinguishment, the Company's balance sheet reflected the face value of the $10 million due to Montaur pursuant to the Montaur Notes, which approximated fair value at the date of the extinguishment.

In June 2010, we entered into a Securities Exchange Agreement with Montaur, pursuant to which Montaur exchanged the Montaur Notes and the Series A Preferred Stock for 10,000 shares of Series B Convertible Preferred Stock (the Series B Preferred Stock), convertible into 32,700,000 shares of common stock. The Series B Preferred Stock is convertible at the option of Montaur, carries no dividend requirements and participates equally with our common stock in liquidation proceeds based upon the number of common shares into which the Series B Preferred Stock is then convertible. As consideration for the exchange, Neoprobe issued additional Series B Preferred Stock which is convertible into 1.3 million shares of common stock.

Also in June 2010, we entered into a Securities Exchange Agreement with the Bupp Investors, pursuant to which the Bupp Investors exchanged the Amended Bupp Note for 1,000 shares of Series C Convertible Preferred Stock (the Series C Preferred Stock), convertible into 3,226,000 shares of common stock. The Series C Preferred Stock has a 10% dividend rate, payable quarterly, and participates equally with our common stock in liquidation proceeds based upon the number of common shares into which the Series C Preferred Stock is then convertible. The exchange of the Montaur Notes, the Series A Preferred Stock and the Amended Bupp Note were treated as extinguishments for accounting purposes. As a result of these exchange transactions, all security interests in the Company's assets held by Montaur and the Bupp Investors were extinguished.

During 2009 the largest aggregate amount outstanding on the Amended Bupp Note was $1.0 million, and, prior to the extinguishment of the Amended Bupp Note on June 25, 2010, the largest aggregate amount of principal outstanding on the Amended Bupp Note during 2010 was $1.0 million. The Company paid $0 of principal outstanding on the Amended Bupp Note during 2009, and $0 of the principal outstanding on the Amended Bupp Note during 2010. The Company paid $100,000 of interest on the Amended Bupp Note during 2009, and $48,611 of interest on the Amended Bupp Note during 2010. During 2009, and prior to the extinguishment of the Amended Bupp Note on June 25, 2010, the Amended Bupp Note accrued interest at the rate of 10% per annum.

In November 2010, we entered into a Securities Purchase Agreement with institutional investors for a registered direct offering of 3,157,896 shares of our common stock at a price of $1.90 per share for total gross proceeds of $6.0 million. In addition to the common stock, we issued one-year Series CC warrants to purchase 1,578,948 shares of our common stock at an exercise price of $2.11 per share, and two-year Series DD warrants to purchase 1,578,948 shares of our common stock at an exercise price of $2.11 per share. As compensation for the services of the placement agent in connection with the offering, we paid the placement agent $420,000 (7% of the gross proceeds) and issued five-year Series EE warrants to purchase 157,895 shares of our common stock at an exercise price of $2.375 per share. The common stock, warrants, and shares of common stock underlying the warrants were issued pursuant to a shelf registration statement on Form S-3 that was declared effective by the Securities and Exchange Commission on August 3, 2010.

The Series CC and Series DD warrants originally contained language that required Neoprobe to classify the warrants as derivative liabilities, and we recorded them at their estimated fair values totaling $1.2 million. In December 2010, a portion of the Series CC and Series DD warrants were modified to remove the language that had previously required them to be classified as derivative liabilities. As a result of the modification of certain of the Series CC and Series DD warrants, we reclassified $801,000 in derivative liabilities related to those warrants to additional paid-in capital. In January 2011, certain investors agreed to modify their outstanding Series CC and Series DD warrants to remove the language that had previously required them to be classified as derivative liabilities. The net effect of marking the derivative liabilities related to the modified Series CC and Series DD warrants to market resulted in net increases in the estimated fair values of the derivative liabilities of $76,000, which were recorded as non-cash expense. As a result of the modification of the Series CC and Series DD warrants, we reclassified $549,000 in derivative liabilities related to those warrants to additional paid-in capital. Between January 1 and March 15, 2011, certain outside investors exercised 1,578,948 Series CC warrants in exchange for issuance of 1,578,948 shares of our common stock, resulting in gross proceeds of $3,331,580. Also between January 1 and March 15, 2011, certain outside investors exercised

799,474 Series DD warrants in exchange for issuance of 799,474 shares of our common stock, resulting in gross proceeds of $1,686,890. The net effect of marking the derivative liabilities related to the exercised Series CC and Series DD warrants to market resulted in net increases in the estimated fair values of the derivative liabilities of $676,000, which were recorded as non-cash expense. As a result of the Series CC and Series DD warrant exercises, we reclassified $1.1 million in derivative liabilities related to those warrants to additional paid-in capital.

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 complete additional clinical testing for Lymphoseek, to file the NDA and to continue our pre-commercialization activities. We believe our current funds will be adequate to sustain our operations at planned levels for the foreseeable future. We are in the process of determining the total development cost necessary to commercialize RIGScan but believe that it will require total additional commitments of approximately $5 million during 2011 to restart manufacturing and other activities necessary to prepare for the clinical trial activities as we currently contemplate them. We expect to use currently available funds to continue the initial steps of restarting manufacturing of RIGScan. We are in the process of evaluating our funding alternatives related to RIGScan, but have not ruled out funding it in connection with a partner. While we have no current plans to raise additional equity capital, we will consider all alternatives available to us as we evaluate our strategic goals and plans. We cannot assure you that we will be successful in raising additional capital at terms acceptable to the Company, or at all. We also cannot assure you that we will be able to successfully obtain regulatory approval for and commercialize new 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. See Risk Factors.

Recent Accounting Developments

In January 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-6, Improving Disclosures about Fair Value Measurements. ASU 2010-6 amends FASB ASC Topic 820, Fair Value Measurements and Disclosures. ASU 2010-6 requires new disclosures as follows: (1) Transfers in and out of Levels 1 and 2 and (2) Activity in Level 3 fair value measurements. An entity should disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for the transfers. In the reconciliation of fair value measurements using significant unobservable inputs (Level 3), an entity should present separately information about purchases, sales, issuances, and settlements (that is, on a gross basis rather than as one net number). ASU 2010-6 also clarifies existing disclosures as follows: (1) Level of disaggregation and (2) Disclosures about inputs and valuation techniques. An entity should provide fair value measurement disclosures for each class of assets and liabilities. A class is often a subset of assets or liabilities within a line item in the statement of financial position. An entity needs to use judgment in determining the appropriate classes of assets and liabilities. An entity should provide disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements. Those disclosures are required for fair value measurements that fall in either Level 2 or Level 3. ASU 2010-6 is effective for interim and annual reporting periods beginning after December 15, 2009, except for the separate disclosures about purchases, sales, issuances, and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. We adopted the initial provisions of ASU 2010-6 beginning January 1, 2010. As the new provisions of ASU 2010-6 provide only disclosure requirements, the adoption of this standard did not impact our consolidated financial position, results of operations or cash flows, but did result in increased disclosures.

In December 2010, the FASB issued ASU 2010-27, Fees Paid to the Federal Government by Pharmaceutical Manufacturers. ASU 2010-27 specifies that the liability for the Company's portion of the annual fee on the pharmaceutical manufacturing industry should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. ASU 2010-27 is effective for calendar years beginning after December 31, 2010, when the fee initially becomes effective. ASU 2010-27 will not impact our consolidated financial position, results of operations or cash flows until the period in which we begin sales of our pharmaceutical products. The effect the adoption of ASU 2010-27 will have on us will depend on the amount of the total annual fee and the amount of Neoprobe's annual sales relative to the total sales of all other U.S. pharmaceutical manufacturers.

Critical Accounting Policies

We consider the following accounting policies to be critical to our results of operations and financial condition.

Revenue Recognition. We currently generate revenue primarily from sales of our gamma detection products. 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. Our customers have no right to return products purchased in the ordinary course of business.

The prices we charge our primary customer, Devicor, related to sales of products are subject to retroactive annual adjustment based on a fixed percentage of the actual sales prices achieved by Devicor on sales to end customers made during each fiscal year. To the extent that we can reasonably estimate the end-customer prices received by Devicor, we record sales to Devicor based upon these estimates. If we are unable to reasonably estimate end customer sales prices related to certain products sold to Devicor, we record revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with Devicor.

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.

We generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due.

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 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. Stock-based payments to employees and directors, including grants of stock options, are recognized in the statements of operations based on their estimated fair values. 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. Compensation cost arising from stock-based awards is recognized as expense using the straight-line method over the vesting period.

38

- 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.

- Fair Value of Derivative Instruments. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated 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. Fair value of warrant liabilities is determined based on a Black-Scholes option pricing model calculation. Fair value of conversion and put option liabilities is determined based on a probability-weighted Black-Scholes option pricing model calculation. Unrealized gains and losses on the derivatives are classified in other expenses as a change in derivative liabilities in the statements of operations. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.

Other Items Affecting Financial Condition

At December 31, 2010, we had deferred tax assets in the U.S. related to net operating tax loss carryforwards and tax credit carryforwards of approximately $31.9 million and $6.0 million, respectively, available to offset or reduce future income tax liabilities, if any, through 2029. However, due to the uncertainty of realizing taxable income in the future, utilization of our tax loss and tax credit carryforwards may be limited. In addition, we believe the ultimate utilization of these tax loss and tax credit carryforwards may be further limited as a result of cumulative ownership changes as defined by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, which have occurred at various points in our history. As a result, the related deferred tax assets have been 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 USA, LLP dated March 16, 2011, 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. Controls and Procedures

Management's Report on Internal Control Over Financial Reporting

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.

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, 2010. 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 are effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, understands that our disclosure controls and procedures do not guarantee that all errors and all improper conduct will be prevented. 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.

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 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. 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, 2010, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2010, 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.

Report of Independent Registered Public Accounting Firm
on Internal Control Over Financial Reporting

Board of Directors
Neoprobe Corporation
Dublin, Ohio

We have audited Neoprobe Corporation's internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Neoprobe Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Report on Internal Control Over Financial Reporting" included in Item 9A. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Neoprobe Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Neoprobe Corporation as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended and our report dated March 16, 2011 expressed an unqualified opinion on those consolidated financial statements.

/s/ BDO USA, LLP

Chicago, Illinois
March 16, 2011

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

Each listed director's respective experience and qualifications described below led the Compensation, Nominating and Governance Committee (CNG Committee) of our Board of Directors to conclude that such director is qualified to serve as a member of our Board of Directors.

Directors whose terms continue until the 2011 Annual Meeting:

Carl J. Aschinger, Jr., age 72, 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 70, 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 71, 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.

Directors whose terms continue until the 2012 Annual Meeting:

Gordon A. Troup, age 57, 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.