NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-K
March 07, 2012

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, 2011

or

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

For the transition period from to _____ to _____

Commission file number H-26520

NAVIDEA BIOPHARMACEUTICALS, INC.
(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 450, 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 x 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 ¨

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, 2011 was $300,597,186.

The number of shares of common stock outstanding on February 17, 2012 was 95,492,330.

DOCUMENTS INCORPORATED BY REFERENCE

None.

References in this report to Navidea Biopharmaceuticals, Navidea, the Company, we, our and us refer to Navidea Biopharmaceuticals, Inc. and its subsidiaries on a consolidated basis. In January 2012, we changed our name to Navidea Biopharmaceuticals, Inc. from Neoprobe Corporation. As discussed more fully below, in connection with the sale of the neoprobe® GDS medical device business and related brand name (Neoprobe) to Devicor Medical Products, Inc. in August 2011, the Company commenced a re-branding initiative reflecting its business pursuits in the precision diagnostics space. Navidea was chosen as the new name to reflect the Company's, dedication to "NAVigating IDEAs" that translate cutting edge innovation and precision diagnostics technology into novel products to advance patient care. Historical references within this Annual Report on Form 10-K to Neoprobe Corporation have therefore generally been revised to refer to our new name.

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this document which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, the ability to obtain, and timing of, regulatory approvals of the Company's products, the timing and anticipated results of commercialization efforts, and anticipated markets for the Company's products, are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of regulatory approvals for and market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, and other risks set forth below under Item 1A, "Risk Factors". The Company undertakes no obligation to publicly update or revise any forward-looking statements.

PART I

Item 1. Business

Development of the Business

Navidea Biopharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative precision diagnostic agents intended to improve diagnostic accuracy, clinical decision-making and patient care. Our Company's core mission is to bring the next generation of precision radiopharmaceutical agents to market so doctors and patients can readily access, and benefit from, cutting-edge diagnostic science.

For patients and physicians, we aspire to provide innovative diagnostic imaging agents to improve patient care for serious diseases. For our shareholders, we aim to deliver superior growth through our focus on our innovative diagnostics platforms and products and efficient business processes. For our employees, we provide a culture focused on the direct impact our efforts can have on patients and an innovative development environment enabling new breakthrough products.

Navidea's current radiopharmaceutical development programs include:

- Lymphoseek® (Lymphoseek, Kit for the Preparation of Technetium Tc99m for Injection), a radiopharmaceutical agent for lymph node mapping, holds great promise for the diagnosis and staging of patients with several different types of solid tumor cancers. Lymphoseek is awaiting clearance to market from the U.S. Food and Drug Administration (FDA).
- AZD4694, a potential best-in-class second-generation imaging agent which may aid in the diagnosis of Alzheimer's disease (AD) and allow patients to seek earlier treatment options.

- RIGScan™, a tumor antigen-specific targeting agent aimed at enhancing the ability of surgeons to detect intraoperatively and thereby remove occult and metastatic tumors in patients with colorectal and other cancers.

Consistent with our strategic vision, we are also evaluating additional opportunities to add to our pipeline and to support our goal of becoming a premier provider of precision diagnostics. To that end, in January 2012, we executed an option agreement with Alseres Pharmaceuticals, Inc. (Alseres) to license [^{123}I]-E-IACFT Injection, also called Altropane®, an Iodine-123 radiolabeled imaging agent, being developed as an aid in the diagnosis of Parkinson's disease, movement disorders and dementia.

A Brief Look at Our History

We were originally incorporated in Ohio in 1983 and reincorporated in Delaware in 1988. We were originally incorporated under the name Neoprobe Corporation and operated under this name until January 2012 when we changed our name to Navidea Biopharmaceuticals, Inc. in connection with the sale of our medical device business and our strategic repositioning as a precision diagnostics company focused on radiopharmaceutical development and commercialization.

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 RIGScan product. Coupled with our limited financial resources at the time, we chose to suspend our radiopharmaceutical development activities and refocus our operating strategy on our medical device business.

In 2002, we acquired a company developing a line of blood flow measurement devices. In 2009, we discontinued the operations of this blood flow measurement device product line and attempted to sell our Cardiosonix Ltd. (Cardiosonix) subsidiary. Attempts to sell Cardiosonix thus far have not been successful. As a result, we have taken steps to complete the shutdown of this subsidiary while meeting the minor service obligations required of medical device manufacturers.

In 2001, we restarted our pharmaceutical development by entering into a worldwide license agreement for Lymphoseek with the Regents of the University of California through their UC, San Diego affiliate (UCSD). In 2004, we initiated our first corporate-sponsored clinical trial of Lymphoseek.

In January 2005 we also formed a new corporation, Cira Biosciences, Inc. (Cira Bio), to explore the development of patient-specific cellular therapies. Navidea owns approximately 90% of the outstanding shares of Cira Bio with the remaining shares being held by the principals of Cira LLC. In connection with refocusing on precision diagnostics, we have suspended further activities in this arena.

From our inception through August 2011, we manufactured a line of gamma radiation detection medical devices called the neoprobe® GDS system (the GDS Business). Prior to July 2010, the GDS products were marketed through a distribution arrangement with Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company. From July 2010 through August 2011, the neoprobe GDS system products were marketed throughout most of the world through a distribution arrangement with Devicor Medical Products, Inc. (Devicor), a successor to EES. During the fiscal years ended December 31, 2011, 2010 and 2009, we derived revenue from the sale of our GDS system products of $7.6 million, $10.0 million, and $9.4 million, respectively, Of those amounts, $7.4 million, $9.8 million, and $8.9 million, respectively, were derived from the sale of our GDS system products in the United States, and $166,000, $182,000, and $472,000, respectively, were derived from the sale of our GDS system products in foreign countries.

In July 2010, Devicor acquired EES's breast biopsy business, including an assignment of the distribution agreement with Navidea. Shortly after this acquisition, Devicor approached us regarding its interest in acquiring the GDS Business. After careful consideration of Devicor's proposal and in-depth discussion regarding the changes this transaction would have on our strategy and focus, the Company's Board of Directors authorized the sale of the GDS Business to Devicor (the Asset Sale) and we executed an Asset Purchase Agreement (APA) with Devicor on May 24, 2011. Our stockholders approved the Asset Sale at our Annual Meeting of Stockholders on August 15, 2011, and the Asset Sale closed on August 17, 2011, consistent with the terms of the APA. Under the terms of the APA, we sold the assets and assigned certain liabilities that were primarily related to the GDS Business. In exchange for the assets of the GDS Business, Devicor made net cash payments to us totaling $30.3 million, assumed certain liabilities of the Company associated with the GDS Business, and agreed to make royalty payments to us of up to an aggregate maximum amount of $20 million based on the net revenue attributable to the GDS Business over the course of the next six fiscal years

In December 2011, we disposed of the extended warranty contracts related to the GDS Business, which were outstanding as of the date of the sale of the GDS Business but were not included in the August 2011 transaction. In exchange for transferring the liability related to the extended warranty contracts to Devicor, we made a cash payment to Devicor of $178,000.

Following the sale of the GDS Business, we have embarked on a journey to transform ourselves as a precision diagnostics company and, as a first step in this transition, we executed the license agreement for AZD4694 in December 2011.

Our Technology and Product Candidates

We have a deep understanding of and experience in translating precision diagnostics technology, particularly in the area of radiopharmaceuticals, into novel products to advance patient care. Innovative precision diagnostic agents hold the potential to improve diagnostic accuracy, clinical decision-making and patient care. Navidea's pipeline includes clinical-stage radiopharmaceutical agents used to identify the presence and status of disease to achieve these objectives.

Lymphoseek – The First Receptor-Targeted Agent for Lymphatic Mapping

Lymphoseek (Kit for the Preparation of Technetium Tc99m for Injection), is a lymph node targeting agent intended for use in intraoperative lymphatic mapping (ILM) procedures and lymphoscintigraphy employed in the overall diagnostic assessment of certain solid tumor cancers. Lymphoseek has the potential to provide oncology surgeons with information to identify key predictive lymph nodes that may harbor cancer and to help avoid the unnecessary

removal of non-cancerous lymph nodes and the surrounding tissue in patients with a variety of solid tumor cancers.

The Lymph System: Infection Fighter and Cancer Conduit

The lymph system is a critical component of the body's immune system. Comprised of a complex network of organs, nodes, ducts and vessels, the lymph system generates and transports lymph – a fluid rich in white blood cells, known as lymphocytes – from tissues into the bloodstream. The key components of the lymph system are lymph nodes – small anatomic structures that contain disease-fighting lymphocytes, filter lymph of bacteria and cancer cells, and signal infection in response to heightened levels of pathogens.

The lymph system is also a common pathway for cancer to spread, or metastasize. In fact, malignant cells will often infiltrate lymph nodes as an initial step of the metastatic process. An assessment of the degree of lymph node involvement is instrumental to staging cancer, enabling suitable treatment regimens and offering more accurate prognosis. Studies in a broad range of malignancies demonstrate that the greater the extent of lymph node involvement, the poorer the likely outcome.

ILM: Targeting High-Risk Nodes

Until the 1990s, cancer patients would often undergo extensive surgeries involving the removal and biopsy of large numbers of lymph nodes to assess disease progress. Studies subsequently showed that as many as 80 percent of node dissections showed no sign of cancer, exposing patients to significant pain, debilitating adverse effects and long recovery times for little benefit.

Over the last two decades, ILM, using injected dyes or radiopharmaceutical agents, has become a widely accepted, less invasive technique to identify potentially cancerous lymph nodes. Upon injection, these tracing agents follow the natural drainage path from the primary tumor into the first tier of surrounding lymph nodes. The initial node(s) in this pathway – or sentinel node(s) – is of critical importance in gauging the degree of infiltration. If this initial node or nodes show no sign of cancer cells, there is a high likelihood that lymph nodes further along the continuum are cancer-free. If the sentinel node is positive for disease, a more comprehensive resection of nodes may be warranted.

Lymphoseek: Tracing the Path to an ILM Advance

ILM has become the cancer-staging procedure of choice for oncology surgeons as it helps them focus on key predictive lymph nodes and reduce patient exposure to unnecessary surgical complications. Lymphoseek is a radiolabeled diagnostic for radio-detection and visualization of the lymphatic system draining the tumor region to delineate lymphatic tissue. Lymphoseek is designed to accumulate in lymphatic tissue by specifically binding to mannose binding receptor (MBR; CD206) proteins present on the surface of immune cells. 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 ligand for the receptor, and the DTPA serves as a chelating agent for labeling with the radio-isotope Technetium Tc 99m.

In clinical studies, Lymphoseek has demonstrated significant benefits over another approved comparator, vital blue dye (VBD). In Navidea's Phase 3 clinical studies of Lymphoseek, it detected over 99 percent of positive nodes identified by VBD. Conversely, VBD missed 31 percent of the overall nodes identified by Lymphoseek and, more importantly, VBD missed 21 percent of nodes identified by Lymphoseek that were subsequently confirmed as containing cancer upon pathology.

We believe Lymphoseek's unique properties in ILM and lymphoscintigraphy offer several potential advantages over agents currently used in ILM, including:

- Improved presence in key predictive lymph nodes
- More rapid clearance of the injection site (up to 8x faster than colloid agents)
- Reduced patient trauma, morbidity and injection pain
- Faster nuclear medicine imaging – reduced nuclear medicine downtime
- Enhanced operating room efficiency; reduced idle OR time
- Enhanced hospital and healthcare plan reimbursement

Expansion of ILM for staging of colon, prostate, gastric, lung and other cancers

The application of ILM to solid tumor cancer management has been most widely developed in the breast cancer and melanoma indications. Numerous clinical studies, involving thousands of patients, 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 sentinel lymph node biopsy (SLNB) is approximately 95% 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 and concomitant morbidity if the sentinel node was found to be free of cancer.

Although ILM has found its greatest acceptance in breast cancer and melanoma, we believe that Lymphoseek may be instrumental in extending ILM into other solid tumor cancers such as prostate, gastric, colon, head and neck, and non-small cell lung. Investigations in these other cancer types have thus far met with mixed levels of success due in part, we believe, to limitations associated with currently available radioactive tracing agents. We believe our development of Lymphoseek may positively impact the effectiveness of ILM in such expanded applications.

Lymphoseek Clinical Development

The initial pre-clinical evaluations of Lymphoseek were completed by UCSD in 2001. Since that time, Navidea, 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. Two comprehensive Phase 3 studies have been completed in subjects with breast cancer and melanoma. These pivotal Phase 3 results have been presented at scientific conferences of a number of the world's leading oncology associations and nuclear medicine societies, including the American Society of Clinical Oncology (ASCO) and the Society for Nuclear Medicine. Earlier-phase studies conducted at UCSD through grants from the Susan B. Komen Breast Cancer Research Foundation have been published in leading medical journals including Journal of Nuclear Medicine and Annals of Surgical Oncology. Clinical research continues with a Phase 3 trial involving subjects with head and neck squamous cell carcinoma.

Lymphoseek development has involved feedback from FDA at a number of stages along the development pathway. In early 2005, the UCSD physician Investigational New Drug (IND) application was transferred to Navidea and we assumed full clinical and commercial responsibility for the development of Lymphoseek. Following the establishment of the corporate IND, Navidea's clinical and regulatory personnel began discussions with FDA regarding the clinical development program for Lymphoseek. Additional non-clinical testing was successfully completed in late 2005 and the reports were filed with FDA in December 2005. These 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 Navidea 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 product and its characterization. Navidea transferred bulk drug manufacturing to Reliable Biopharmaceutical Corporation (Reliable) and engaged OSO BioPharmaceuticals Manufacturing LLC (OSO Bio, formerly Cardinal Health PTS) for commercial manufacturing of the drug product. Our CMC response to FDA was submitted 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 and began patient enrollment in September 2006. Enrollment of 80 patients was completed in June 2007 and we announced positive preliminary efficacy and final results in June and December 2007, respectively. 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 and results of the 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 designed to evaluate the safety and the accuracy of Lymphoseek in identifying the lymph nodes draining from the subject's primary tumor site. The primary efficacy objective of the study was a statistically acceptable concordance rate between the identification of lymph nodes with VBD and Lymphoseek. In addition, a secondary endpoint of the study was to pathologically examine lymph nodes identified by either VBD or Lymphoseek to determine if cancer was present in the lymph nodes.

In June 2009, we initiated a second Phase 3 trial in subjects with head and neck squamous cell carcinoma (NEO3-06). The NEO3-06 study was designed to expand the potential labeling for Lymphoseek to include a sentinel lymph node targeting claim, after the initial marketing clearance for general lymphatic mapping. The accrual rate for this trial is slower than for the NEO3-05 and NEO3-09 trials due in part to the lower incidence rate for head and neck cancers for subjects eligible for this trial.

In March 2010, Navidea met with FDA to review the clinical outcomes of the NEO3-05 Phase 3 trial. The meeting included a review of the efficacy and safety results of the study and Navidea's plans for the submission of a New Drug Application (NDA) for Lymphoseek based on the results of NEO3-05 and other previously completed clinical studies. In July 2010, Navidea initiated enrollment in another Phase 3 clinical evaluation of Lymphoseek in subjects with either breast cancer or melanoma (NEO3-09) accruing subjects primarily for purposes of augmenting the safety population and supporting 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, Navidea 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 then 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.

In February 2011, we announced that we had accrued an adequate number of subjects to enable us to meet the lymph node accrual goal for NEO3-09. Top-line data from NEO3-09 were released during the second quarter of 2011, indicating that all primary and secondary endpoints for the study were met and demonstrating strong agreement with the previously successful NEO3-05 clinical study. Navidea submitted the NDA for Lymphoseek in August 2011, and was notified of acceptance of the NDA by FDA in October 2011. The Lymphoseek NDA submission was based on the clinical results of the NEO3-05 and NEO3-09 Phase 3 clinical studies and other completed clinical and non-clinical evaluations. The safety database submitted with the NDA included data from over five hundred subjects and identified no significant drug-related adverse events. In the letter from FDA notifying the Company of the acceptance of Lymphoseek NDA, FDA established a Prescription Drug User Fee Act (PDUFA) date for Lymphoseek of June 10, 2012. Depending on the timing and outcome of the FDA regulatory review cycle, we believe that Lymphoseek can be commercially launched in the second half of 2012.

As noted above, our third Phase 3 clinical trial for Lymphoseek in subjects with head and neck squamous cell carcinoma (NEO3-06) is currently in progress. The NEO3-06 clinical study was designed to expand the potential label for Lymphoseek as a SLNB agent after the initial marketing clearance for the product. However, based on the acceptance of the NDA by FDA, we now believe we do not need to complete the NEO3-06 study. Rather, we now believe an interim analysis may be achieved in mid-2012.

Navidea was also advised in February 2012 by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) that the Committee has adopted the advice of the Scientific Advice Working Party (SAWP) regarding the Lymphoseek development program and has determined that Lymphoseek is eligible for a Marketing Authorization Application (MAA) submission based on clinical data accumulated from completed pivotal studies and supporting clinical literature. As such, we intend to submit our MAA to the EMA by the end of 2012.

We cannot assure you, however, that Lymphoseek will achieve regulatory approval in the U.S., the EU or any market, or if approved, that it will achieve market acceptance. See Risk Factors.

AZD4694 – Precision Imaging Agent to Aid in Diagnosis of Alzheimer's Disease

AZD4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate for use in the imaging and evaluation of patients with signs or symptoms of cognitive impairment such as AD. It binds to beta-amyloid deposits in the brain that can then be imaged in positron emission tomography (PET) scans. Amyloid plaque pathology is a required feature of AD and the presence of amyloid pathology is a supportive feature for diagnosis of probable AD. Patients who are negative for amyloid pathology do not have AD.

Based on the data accumulated to date, AZD4694 appears to have better sensitivity in detecting beta-amyloid than other agents in development. Due to its high affinity for amyloid, improved contrast, and enhanced uptake in the amyloid-target regions of interest in the brain compared with that in white matter background for amyloid, which is very low, better signal-to-noise ratios have been observed. The uptake in background tissue, referred to as white matter, is low. Greater sensitivity and contrast may allow detection of smaller amounts of amyloid and may enable earlier identification of disease pathology, as well as providing the opportunity to detect smaller changes in amyloid levels in monitoring disease progression over time.

Beta-Amyloid Imaging for Alzheimer's Disease

Alzheimer's disease is a progressive and fatal neurodegenerative disease which affects a person's memory and ability to learn, reason, communicate and carry out daily activities. Increasing age is the greatest risk factor for AD and there is no prevention or cure. The World Health Organization estimates that AD affects over 24 million people worldwide. Currently in the U.S. alone, there are over 5 million Alzheimer's patients and according to Alzheimer's Association (AA) estimates, as many as 16 million Americans could have the disease by 2050. Among the brain changes evident in the development of AD is the accumulation of the protein beta-amyloid outside nerve cells (neurons) in the brain. Somewhere around 100 experimental therapies aimed at slowing or stopping the progression of AD are now undergoing clinical evaluation. Regardless of causative associations, beta-amyloid levels continue to be viewed as a reliable marker of AD.

There is a need for improvements in testing and diagnosis for AD. While there is an accepted diagnostic process for assessing dementia, the only currently definitive diagnosis for AD is a post-mortem analysis of brain tissue. A positive finding of plaques and tangles in the brain upon autopsy leads to this definitive diagnosis, which is too late to benefit the patient. For this reason, the AD and imaging communities have been interested in an effective biomarker of AD which could facilitate earlier definitive diagnosis.

Alzheimer's disease imaging agents are potentially powerful tools aiding in the diagnosis of AD as well as the evaluation of new drugs aiming to modify amyloid plaque levels and alter disease progression. The prototype agent in this diagnostic quest was identified almost a decade ago at the University of Pittsburgh. This imaging agent targets the deposits of amyloid plaque which are a hallmark of AD pathology. This agent, frequently referred to as Pittsburgh B, or PIB, is a radiolabeled small molecule utilized with PET imaging. As such, the PIB tracer provided strong image resolution and was able to distinguish significant amyloid burdens in the brains of AD patients as opposed to the relative absence of amyloid in subjects without AD. Unfortunately, PIB uses C-11, a very short-lived radio-isotope, and thus cannot be readily commercialized.

Other PET amyloid tracers are currently moving through the drug development process. These compounds also have the high resolution of PET tracers, but utilize an F-18 isotope, which permits effective broad distribution.

These agents constitute a major step forward, but each has potential limitations. Navidea's AZD4694 appears to have several important advantages including clean images with less white matter uptake for identification of lower levels of amyloid and earlier detection; images that are easier to read and interpret; and images that can be acquired more quickly.

AZD4694 Clinical Development

AZD4694 has been studied in several clinical trials. Clinical studies through Phase 2a have included more than 80 patients to date, both suspected AD patients and healthy volunteers. No significant adverse events have been observed. Results suggest that AZD4694 has the ability to image patients quickly and safely with high sensitivity. Importantly, AZD4694 seems to exhibit low background and white matter uptake, thereby providing clear images of beta amyloid deposits.

We are in the process of refining our development plans for AZD4694 but intend to initiate new Phase 2 trials in 2012, primarily to expand the safety database for the compound and to initiate a Phase 3 trial in 2013 to support registration in the U.S. and the EU. We cannot assure you, however, that further clinical trials for this product will be successful, that it will achieve regulatory approval, or if approved, that it will achieve market acceptance. See Risk Factors.

RadioImmunoGuided Surgery (RIGS)

The eradication of all tumor cells is the ultimate goal in the surgical treatment of cancer patients. However, even after radical and potentially curative surgery coupled with post-operative treatment, a high percentage of patients develop metastatic or recurrent disease. This is particularly true for colorectal cancer where an estimated 30 percent of node negative or Stage 2 patients develop recurrent disease within 24 – 30 months of their initial surgery.

RIGS is a technique to provide real-time diagnostic information during cancer surgery. RIGS is intended to enable a surgeon to identify and delineate cancerous tissue “targeted” through the use of a radiolabeled, cancer-specific targeting antibody, administered prior to surgery and identified during surgery with a gamma detection device/probe. This procedure assists a surgeon in identifying the location of cancerous tissues in real time (during surgery) to enable more thorough surgical removal for better patient outcomes. Before surgery, a cancer patient is injected with the antibody which circulates throughout the patient’s body and binds specifically to cancer cell antigens or receptors. Concentrations of the antibody within affected tissue are then detected using a gamma probe and direct the surgeon to targeted tissue for removal.

RIGScan development to-date has been based on an intraoperative biologic targeting agent consisting of a radiolabeled murine monoclonal antibody (CC49 MAb, Minretumomab). The CC49 MAb localizes or binds to TAG-72 antigen. RIGScan 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 is intended to provide the surgeon with a more accurate assessment of the extent of disease, and therefore may impact the surgical and therapeutic management of the patient.

RIGScan Clinical Development

RIGScan has been studied in several clinical trials, including Phase 3 studies. Results from certain of these studies have been published in leading cancer journals including Clinical Cancer Research, Annals of Surgical Oncology and Disease of the Colon and Rectum. Navidea conducted two Phase 3 studies, NEO2-13 and NEO2-14, of RIGScan 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.

In 1996, Navidea submitted applications to EMA and FDA for marketing approval of RIGScan for the detection of metastatic colorectal cancer based primarily on results NEO2-14, considered to be the pivotal study in support of the RIGScan Biologic License Application (BLA). 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 and potential removal of additional tumor provided clinical benefit that altered patient management or outcome for patients with metastatic 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. Navidea withdrew its application to EMA in November 1997.

We continued over the intervening years to identify a pathway to regulatory approval for RIGScan. Despite additional data developed subsequent to the BLA filings, including data in 2004 indicating that RIGScan status was correlated with patient survival trends and that RIGScan may be predictive of a positive outcome when measuring survival of the patients that participated in our original BLA studies, and submission of an IND amendment to FDA which included the design of a proposed Phase 3 clinical trial of RIGScan, we were not able to advance RIGScan in clinical development.

To further support resumed RIGScan development, we filed a new IND request for the biologic component of the RIGS technology in late 2010. We held a pre-IND meeting with FDA in February 2011 to define the basic CMC requirements needed to resume clinical development efforts on RIGScan. FDA reviewed Navidea's comprehensive pre-IND package and provided direction to the Company on its clinical and manufacturing activities going forward. As an outcome of the pre-IND meeting, FDA provided guidance regarding enhancing our manufacturing platform, including process improvements to increase manufacturing efficiency and the quality of the underlying biologic antibody and potentially transitioning from a murine-based antibody to a human-based antibody. In August 2011, we also held a meeting with the SAWP of the EMA and received similar guidance as we received from FDA, as well as the suggestion that we consider use of a humanized version of the RIGS antibody. With this collective guidance, we have changed from a murine antibody to a humanized antibody on our development and regulatory timelines. We believe that we may still be technically able to complete the necessary manufacturing steps to permit active clinical development by the end of 2012; however, as management continues to assess the scope and required resources for the RIGS program, particularly in light of other development opportunities such as for AZD4694 and/or [^{123}I]-E-IACFT, the timing and scope of our development and commercialization plan for RIGScan may be affected.

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. During the third quarter of 2009, we had announced that we executed a Biopharmaceutical Development and Supply Agreement with Laureate Biopharmaceutical Services, Inc. (Laureate Biopharma). This agreement also supports manufacturing process development work, evaluation of the CC49 master working cell bank, and the initial steps in re-validating the clinical grade and commercial production process for a humanized version of the RIGScan antibody. Laureate Biopharma has made progress in the re-validation of the manufacturing process and has completed certain biologic characterization activities. Our development plans for RIGScan also include the consideration of alternative radiolabeling processes. We will need to establish manufacturing and radiolabeling capabilities for the CC49 antibody in order to meet the regulatory needs for the RIGScan product.

We continue to believe it may be advantageous for us to identify a development partner for RIGScan. We have engaged in discussions with various parties over the past few years regarding potential partnerships and/or other development arrangements. 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 satisfactory development arrangements with a partner or obtain incremental 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 further clinical development will be successful, that FDA or EMA will clear RIGScan for marketing, or that it will be

successfully introduced or achieve market acceptance. See Risk Factors.

[^{123}I] E-IACFT (Under Option)

in January 2012, we executed an option agreement with Alseres to license [^{123}I]-E-IACFT Injection, also called Altropane, an Iodine-123 radiolabeled imaging agent, being developed as an aid in the diagnosis of Parkinson's disease, movement disorders and dementia. The option agreement provides Navidea with exclusive rights for a period of up to six months to perform final due diligence and prepare the documentation necessary to enter into a definitive license agreement for [^{123}I]-E-IACFT. Under the terms of the option agreement, Navidea paid Alseres an option fee of $500,000 for the exclusive right to negotiate a definitive license agreement by June 30, 2012. Navidea can extend the option period from June 30, 2012, to July 31, 2012, for an additional $250,000. The option agreement anticipates that Navidea will issue Alseres 400,000 shares of Navidea common stock upon execution of the definitive license agreement. The option also anticipates that the license agreement will provide for contingent milestone payments of up to $3.0 million, $2.75 million of which will occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.05 million shares of Navidea stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the license terms outlined in the option agreement anticipate royalties on net sales of the approved product which are consistent with industry-standard terms.

[^{123}I]-E-IACFT is a patented, novel, small molecule radiopharmaceutical used with single photon emission computed tomography (SPECT) imaging to identify the status of specific regions in the brains of patients suspected of having Parkinson's disease. The agent binds to the dopamine transporter (DAT) on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a widely recognized hallmark of Parkinson's disease.

[^{123}I]-E-IACFT has been administered to over 600 subjects to date. A Phase 3 Special Protocol Assessment (SPA) for [^{123}I]-E-IACFT is already in place with FDA and over 50 subjects have been enrolled to establish a training data base. Results from clinical trials have demonstrated that [^{123}I]-E-IACFT has high affinity for DAT and rapid kinetics which enable the generation of clean images quickly, beginning within about 20 minutes after injection while other agents typically have waiting periods from 4 to 24 hours before imaging can occur. In addition to its potential use as an aid in the differential diagnosis of Parkinson's disease and movement disorders, [^{123}I]-E-IACFT may also be useful in the diagnosis of Dementia with Lewy Bodies (DLB), one of the most common forms of dementia after AD.

Market Overviews

Cancer Market Overview

Cancer is the second leading cause of death in the U.S. and Western Europe and is estimated by the American Cancer Society (ACS) to be responsible for over 577,000 deaths annually in 2012 in the U.S. alone. The NIH has estimated

the overall annual costs for cancer for the U.S. for 2007 at $226.8 billion: $103.8 billion for direct medical costs and $123.0 billion for indirect mortality. For the types of cancer to which our oncology agents may be applicable (breast, melanoma, head and neck, prostate, lung, colorectal, gastrointestinal and gynecologic), the ACS has estimated over 1.2 million new cases will occur in the U.S. in 2012. An analysis of Globocan 2010 estimates for these same cancer types indicates an annual incidence rate for these cancer types in excess of 7.2 million cases.

Currently, the application of ILM is most established in breast cancer. 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 some overall decline in the past few years, generally increases with age, rising from about 1.5 cases per 100,000 women from age 20 to 24 to 421 cases per 100,000 women at age 75 - 79. 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 230,000 new cases of invasive breast cancer are expected to be diagnosed during 2012 in the U.S. alone. Thus, we believe that the 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. 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 assist in the clinical evaluation and staging of solid tumor cancers and expanding lymph node mapping to additional types of cancer, such as prostate, colon, non-small cell lung and other solid tumor cancers. However, we cannot assure you that Lymphoseek will be cleared to market, or if cleared to market, that it will achieve significant revenue. See Risk Factors.

Alzheimer's Disease Market Overview

The AA estimates that more than 5.4 million Americans had AD in 2011. On a global basis, Alzheimer's Disease International estimated in 2010 that there were 35.6 million people living with dementia. AA also estimates that there are nearly 15 million AD and dementia caregivers providing 17 billion hours of unpaid care valued at $202 billion. AD is the sixth-leading cause of death in the country and the only cause of death among the top 10 in the U.S. that cannot be prevented, cured or even slowed. Based on mortality data from 2000-2008, death rates have declined for most major diseases while deaths from AD have risen 66 percent during the same period.

While there are several approved therapies for the treatment of AD, there is significant interest in the development of disease-modifying therapeutics that could slow or reverse progression of the disease. In fact, studies with cholinesterase inhibitors and experimental AD therapies suggest therapeutic intervention is likely to have a bigger impact on disease progression when dosed in patients with early-stage disease than in patients with advanced disease.

For many patients, simply slowing the progression from mild cognitive impairment associated with early-stage disease to advanced AD could have a material impact on quality of life and medical burden for the healthcare system. Delaying the onset of AD by 5 years would reduce the number of Americans living with the disease in the U.S.in 2050 from 13.5 million to 7.7 million, according to estimates from AA.

While early detection is the goal of AD staging, there are no validated biomarkers for the onset of symptomatic disease. All AD patients have beta-amyloid plaque deposits in the brain. Currently, detection of the early-stages of AD is based largely on assessing the patient's history of increasing cognitive impairment with some patients also receiving testing by an experimental PET scan to confirm the presence of amyloid plaque. The interest in accurate imaging agent biomarkers for the detection of beta-amyloid has grown significantly in recent years as physicians are attempting to identify methods for detecting amyloid earlier.

Marketing and Distribution

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 or neurological pharmaceutical portfolios may also have interest. Examples of entities with established regional and/or global radiopharmaceutical distribution networks include Cardinal Health, Covidien, General Electric Healthcare, IBA, AAA, E&Z AG, Lantheus Medical Imaging and Bracco.

During the fourth quarter of 2007, we executed an agreement with Cardinal Health's Nuclear Pharmacy Services division for the exclusive distribution of Lymphoseek in the U.S. The agreement is for a term of five years from the date of NDA marketing clearance from FDA. Under the terms of this agreement, Navidea will receive a significant share of the revenue from each patient dose of Lymphoseek sold. In addition, Navidea will receive up to $3 million in payments upon the achievement of certain sales milestones by Cardinal Health. We cannot assure you that we will be able to maintain a successful relationship with Cardinal Health, on terms acceptable to the Company or at all.

We are in various stages of discussion with potential marketing and distribution partners in the EU and other world markets; however, we do not currently have distribution agreements covering Lymphoseek in any areas of the world other than the U.S. We currently have no distribution agreements for AZD4694 or RIGScan. In addition, it should be noted that the distribution model we have established with Cardinal Health in the U.S. for Lymphoseek may not necessarily be applicable to other markets or even our other potential radiopharmaceutical candidates due to differences in regional distribution infrastructure, regulation and medical practice patterns. 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.

Manufacturing

We currently use and expect to continue to be dependent upon contract manufacturers to manufacture each of our product candidates. We have established a quality control and quality assurance program, including a set of standard operating procedures and specifications with the goal that our products and product candidates are manufactured in accordance with current Good Manufacturing Practices (cGMP) and other applicable domestic and international regulations. We will need to invest in additional manufacturing and supply chain resources, and may seek to enter into additional collaborative arrangements with other parties that have established manufacturing capabilities. It is likely that we will continue to rely on third-party manufacturers for our development and commercial products on a contract basis.

Lymphoseek Manufacturing

In preparation for the commencement of a multi-center clinical evaluation of Lymphoseek, Navidea engaged manufacturing organizations to produce drug used in Phase 2 and Phase 3 trials, 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 (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 (radiolabeled) with Technetium 99m (Tc99m) to become the final form of Lymphoseek to be administered to a patient. The commercial manufacturing processes at Reliable and OSO Bio have been validated and both organizations have assisted Navidea in the preparation of the CMC 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 a commercial supply agreement with OSO Bio on terms satisfactory to us, or at all.

AZD4694 Manufacturing

Supplies of AZD4694 used in clinical development to date have been manufactured by AstraZeneca through various arrangements. As a part of the technology transfer process related to our license of AZD4694, we have begun the process of identifying third party manufacturers and radiolabeling contractors necessary to produce the drug product for use in further clinical studies as well as for subsequent commercial use.

RIGScan Manufacturing

During the third quarter of 2009, we announced that we had executed a Biopharmaceutical Development and Supply Agreement for RIGScan with Laureate Biopharma. This agreement supports the initial evaluation of the viability of the CC49 master and working cell banks as well as the initial steps in validating the commercial production process for the humanized RIGScan antibody. In addition, we will need to re-establish radiolabeling capabilities for the antibody in order to meet the regulatory needs for the RIGScan product.

Summary

We cannot assure you that we will be successful in securing and/or maintaining the necessary manufacturing, supply and/or radiolabeling capabilities for our product candidates in clinical development. If and when established, 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.

Competition

Competition in the pharmaceutical and biotechnology industries is intense. We face competition from a variety of companies focused on developing oncology and neurology diagnostic drugs. We compete with large pharmaceutical and other specialized biotechnology companies. We also face competition from universities and other non-profit research organizations. Many emerging medical product companies have corporate partnership arrangements with large, established companies to support the research, development, and commercialization of products that may be competitive with our products. In addition, a number of large established companies are developing proprietary technologies or have enhanced their capabilities by entering into arrangements with or acquiring companies with technologies applicable to the detection or treatment of cancer and other diseases targeted by our product candidates. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of these competitors have products that have been approved or are in development and operate large, well-funded research and development programs. 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 ours. See Risk Factors.

We expect to encounter significant competition for the principal pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before us may achieve a significant competitive advantage if their products work through a similar mechanism as our products and if the approved indications are similar. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us. In some instances, such products have already entered late-stage clinical trials or received FDA approval and may be marketed for some period prior to the approval of our products.

We believe that our ability to compete successfully will be based on our ability to create and maintain scientifically advanced “best-in-class” technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market our products, either alone or through third parties. We will continue to seek licenses for technologies related to our field of interest and may face competition with respect to such efforts. 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.

Specific Competitors to Lymphoseek

Surgeons who practice the lymphatic mapping procedure for which Lymphoseek is intended currently use other radiopharmaceuticals such as a sulfur 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 around a primary tumor. In the U.S., sulfur colloid is manufactured by Pharmalucence. Sulfur colloid had been used “off-label” in the U.S. for ILM until July 2011, when it was approved by FDA for use in lymphatic mapping in breast cancer patients based on a statistical meta-analysis of published literature that compared the use of sulfur colloid with that of the vital blue dyes. In the European Union and certain Pacific Rim markets, there are other colloidal-based compounds with various levels of approved labeling for use in lymphatic mapping although a number of countries still employ the use of products used “off-label”.

Imaging Agents in Clinical Development for AD

Several potential competitive F-18 products are in development for use as biomarkers to aid in detection of AD. Developed through Eli Lilly's wholly-owned Avid Radiopharmaceuticals (Avid), florbetapir (AV-45) was reviewed on January 20, 2011 by the FDA Peripheral and Central Nervous System Drugs Advisory Committee, which voted 16-0 in favor of recommending that this drug be approved for use. However, the recommendation was contingent on a training program as there was significant variability in interpretation among readers of images generated by this agent. On March 18, 2011, Avid received an FDA Complete Response letter primarily focused on the need to establish a reader training program to ensure reader accuracy and consistency of interpretations of existing florbetapir scans. Eli Lilly has responded to these concerns and the drug is expected to be approved in the near future. In addition to fluorbetipir, there are two other beta-amyloid imaging agents in late stage development: florbetaben from Bayer Schering and flutemetamol from General Electric. Both have completed Phase 3 trials. Data from the 232-patient Phase 3 study of florbetaben is expected in August 2012, according to FDA's website. The study was designed to evaluate the power of florbetaben to identify whether a suspected AD patient has cerebral beta-amyloid deposits. The data will be verified by histological verification in a postmortem autopsy. GE Healthcare is developing another PIB derivative, flutemetamol, for similar application. Results of the Phase II flutemetamol study were published in a January 2011 issue of the JAMA with an accompanying editorial.

RIGScan Competition

We do not believe there are any intraoperative diagnostic radiopharmaceuticals directly competitive with RIGScan that would be used in the colorectal cancer application at which RIGScan is initially targeted. 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.

Patents and Proprietary Rights

The patent position of biotechnology, 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 or those licensed to us will result in additional patents being issued or that any of our patents or those licensed to us will afford protection against competitors with similar technology; nor can we assure you that any of these 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.

Lymphoseek Intellectual Property

Lymphoseek is being developed under exclusive worldwide license from the Regents of the University of California through their UCSD affiliate. The UCSD license grants Navidea the commercialization rights to Lymphoseek for diagnostic imaging and intraoperative detection applications.

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 Navidea 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 U.S. related to manufacturing processes for Lymphoseek. We will also rely on trademark protection for products that we expect to commercialize and have registered the mark Lymphoseek® in the U.S. and other markets.

AZD4694 Intellectual Property

AZD4694 is being developed under exclusive worldwide license from AstraZeneca. The AZD4694 license grants Navidea commercialization rights to the F-18 labeled biomarker for use as an aid in the diagnosis of AD. AZD4694 is the subject of two issued patents in the U.S. and one other patent issued worldwide to date but is the subject of an nearly 60 additional patent applications on a worldwide basis.

RIGScan Intellectual Property

We continue to support proprietary protection for the products related to RIGS 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 and we could lose these license rights if we don’t diligently pursue commercialization of the patented technology. Additionally, statutory exclusivity exists for biologics upon approval in the U.S. for 12 years. In the EU, data exclusivity extends for 10 years following marketing authorization.

Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA), Public Health Service Act (PHSA), and their implementing regulations. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications or supplemental applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution. We also may be subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Export Control Act and other present and future laws of general application as well as those specifically related to radiopharmaceuticals.

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, quality, safety, efficacy and labeling of such products, the maintenance of certain records, the tracking of such products, performance surveillance 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 radiopharmaceuticals 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 a noncompliance notification or warning letter 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. See Risk Factors.

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, the FDA Modernization Act of 1997 (the 1997 Act) was adopted with the intent of bringing better definition to the clearance process for new medical products. While FDA review times have improved since passage of the 1997 Act, we cannot assure you that FDA review processes will not 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 development and 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. See Risk Factors.

The Drug Approval Process

None of our drugs may be marketed in the U.S. until such drug has received FDA approval. The steps required before a drug may be marketed in the U.S. include:

- preclinical laboratory tests, animal studies and formulation studies;
- submission to FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational product for each indication;
- submission to FDA of an NDA;

- satisfactory completion of FDA inspections of the manufacturing and clinical facilities at which the drug is produced, tested, and/or distributed to assess compliance with cGMPs and cGCP standards; and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA unless, before that time, FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board at each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase 1 usually involves the initial introduction of the investigational product into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage, (ii) identify possible adverse effects and safety risks, and (iii) evaluate preliminarily the efficacy of the product candidate for specific indications. Phase 3 trials usually further evaluate clinical efficacy and further test its safety by using the product candidate in its final form in an expanded patient population. There can be no assurance that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we or FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

FDA and the IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA application. This process is known as a special protocol assessment, or SPA. These agreements may not be changed after the clinical studies begin, except in limited circumstances. The existence of a SPA, however, does not assure approval of a product candidate.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacturing quality and composition of the investigational product, are submitted to FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort and financial resources. Submission of an NDA requires payment of a substantial review user fee to FDA. The NDA for Lymphoseek, intended for use in intraoperative lymphatic mapping across a broad range of cancers, is currently under review by FDA. As a part of that review, FDA is reviewing the pre-clinical, clinical and CMC data supporting our application, and, as is also typical of such reviews, is conducting site audits of our facilities and those of the sites where the referenced clinical trials were performed, as well as of contract suppliers and third party vendors being used in the manufacturing and quality assessment processes for Lymphoseek. Such audits, or other inquiries by FDA, could raise questions or issues, requiring us to prepare responses or submit additional data that could delay approval of our NDA beyond our expected PDUFA date. If such questions or issues are raised formally through FDA’s issuance of a Complete Response Letter, it would be necessary for us to amend the NDA before it could be approved, a process that would further delay FDA approval. While we continue to believe that the NDA for Lymphoseek is ultimately approvable, it is possible that approval could be delayed as a result of FDA’s review process. Any delay in the approval of the NDA could result in delays in our expected revenue from Lymphoseek and increase the use of our cash until any deficiencies cited by FDA are corrected and an amended NDA submitted and reviewed by FDA. In the review process for NDAs in general, FDA may also seek the advice of an advisory committee, typically a panel of

clinicians practicing in the field for which the product is intended, for review, evaluation and a recommendation as to whether the application should be approved. FDA is not bound by the recommendations of the advisory committee. To date, we have not been notified by FDA as to whether there will be an advisory committee convened related to Lymphoseek. See Risk Factors.

FDA has various programs, including fast track, priority review and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life threatening conditions, those with the potential to address unmet medical needs and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, the review time will be reduced or the product will be approved.

Before approving a NDA, FDA usually will inspect the facility or the facilities where the product is manufactured, tested and distributed and will not approve the product unless cGMP compliance is satisfactory. If FDA evaluates the NDA and the manufacturing facilities as acceptable, FDA may issue an approval letter, or in some cases, a complete response letter. A complete response letter contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to FDA's satisfaction, FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of approval, FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy, or impose other post-approval commitment conditions.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted.

In June 2011, an investor in our Company with an acknowledged short interest in our common stock filed a Citizen Petition with FDA requesting that FDA not accept our NDA for Lymphoseek on the basis that our application did not include a clinical comparison to sulfur colloid or full regional nodal dissection. We filed a response to FDA, also in June 2011, refuting the claims on which the Citizen Petition was based. In August 2011, we filed the NDA for Lymphoseek. The NDA was accepted by FDA for review in October 2011. FDA subsequently responded to the investor informing him they had no timetable for addressing his petition. We believe the FDA acceptance of the NDA, as well as the active review process underway related to the NDA, largely negate the arguments made by the investor in the Citizen Petition.

Post-Approval Requirements

Holders of an approved NDA are required to: (i) conduct pharmacovigilance and report certain adverse reactions to FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP. FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing and distribution facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production, quality control and distribution to maintain cGMP compliance. We use and will continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market.

Marketing of prescription drugs is also subject to significant regulation through federal and state agencies tasked with consumer protection and prevention of medical fraud, waste and abuse. We must comply with restrictions on off-label

use promotion, anti-kickback, ongoing clinical trial registration, and limitations on gifts and payments to physicians.

Non-U.S. Regulation

Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all EU members' states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

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.

Regulation Specific to 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 require post-marketing reporting and surveillance programs (pharmacovigilance) 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.

The Nuclear Regulatory Commission (NRC) oversees medical uses of nuclear material through licensing, inspection, and enforcement programs. The NRC issues medical use license to medical facilities and authorized physician users, develops guidance and regulations for use by licensees, and maintains a committee of medical experts to obtain advice about the use of byproduct materials in medicine. The NRC (or the responsible Agreement State) also regulates the manufacture and distribution of these products. FDA oversees the good practices in the manufacturing of radiopharmaceuticals, medical devices, and radiation-producing x-ray machines and accelerators. The states regulate

the practices of medicine and pharmacy and administer programs associated with radiation-producing x-ray machines and accelerators. We, or our manufacturer of the radiolabeled antibodies, must obtain a specific license from the NRC (or the responsible Agreement State) 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.

Corporate Information

Our executive offices are located at 425 Metro Place North, Suite 450, Dublin, Ohio 43017. Our telephone number is (614) 793-7500. “Navidea”, the Navidea logo, “Lymphoseek”, “RIGS” and “RIGScan” are trademarks of Navidea Biopharmaceuticals, Inc. or its subsidiaries in the U.S. and/or other countries. Other trademarks or service marks appearing in this report may be trademarks or service marks of other owners.

The address for our website is http://www.navidea.com. We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings pursuant to Section 13(a) or 15(d) of the Exchange Act, and amendments to such filings, as soon as reasonably practicable after each is electronically filed with, or furnished to, the SEC.

Research and Development

We spent approximately $15.2 million, $8.9 million and $4.4 million on research and development activities in the years ended December 31, 2011, 2010 and 2009, respectively.

Employees

As of March 1, 2012, we had 32 full-time and 9 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 report, including our financial statements and the related notes, before you decide to buy our common stock. Our most significant risks and uncertainties are described below; however, they are not the only risks we face. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading of our common stock could decline, and you may lose all or part of your investment therein.

We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates and our approval to market our products may be delayed as a result of the regulatory review process.

Obtaining regulatory approval to market drugs to diagnose or treat cancer is expensive, difficult and risky. Preclinical and clinical data as well as information related to the CMC processes of drug production can be interpreted in different ways which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval.

Our near-term financial success depends in large part on obtaining regulatory approval to market Lymphoseek in the U.S. The NDA for Lymphoseek intended for use in intraoperative lymphatic mapping across a broad range of cancers, is currently under review by FDA. As a part of that review, FDA is reviewing the pre-clinical, clinical and CMC data supporting our application, and, as is also typical of such reviews, is conducting site audits of our facilities and those of the sites where the referenced clinical trials were performed, as well as of contract suppliers and third party vendors being used in the manufacturing and quality assessment processes for Lymphoseek. Such audits, or other inquiries by FDA, could raise questions or issues, requiring us to prepare responses or submit additional data that could delay approval of our NDA beyond our expected PDUFA date. If such questions or issues are raised formally through FDA's issuance of a Complete Response Letter, it would be necessary for us to amend the NDA before it could be approved, a process that would further delay FDA approval. While we continue to believe that the NDA for Lymphoseek is ultimately approvable, it is possible that approval could be delayed as a result of FDA's review process. Any delay in the approval of the NDA could result in delays in our expected revenue from Lymphoseek and increase the use of our cash until any deficiencies cited by FDA are corrected and an amended NDA is submitted and reviewed by FDA. Such potential consequences may negatively affect our business, financial condition and results of operations in a material way.

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, any contract manufacturer we use the process of producing a 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.

Even if our drug candidates are successful in clinical trials, we may not be able to successfully commercialize them.

With the historical exception of our discontinued medical device businesses, we have dedicated and will continue to dedicate substantially all of our resources to the research and development of our radiopharmaceutical technologies and related compounds. All of our compounds currently are in research or development or regulatory review and have not received marketing approval.

Prior to commercialization, each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. The development of radiopharmaceutical technologies and compounds, including those we are currently developing, is unpredictable and subject to numerous risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons including that they may:

- be found ineffective or cause harmful side effects during preclinical testing or clinical trials;
- fail to receive necessary regulatory approvals;
- be difficult to manufacture on a scale necessary for commercialization;
- be uneconomical to produce;

- fail to achieve market acceptance; or
- be precluded from commercialization by proprietary rights of third parties.

The occurrence of any of these events could adversely affect the commercialization of our product candidates. Products, if introduced, may not be successfully marketed and/or may not achieve customer acceptance. If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.

We divested our primary commercial product line, the neoprobe GDS line of gamma detection medical devices, in August 2011. Currently, we do not have any revenue generating products, and unless we are able to develop one of our product candidates, such as Lymphoseek, into an approved commercial product, we will not generate any significant revenues from product sales, milestone payments or otherwise. The NDA for Lymphoseek is currently under review by FDA and AZD4694 and RIGScan are in various stages of clinical development. Regulatory approval for Lymphoseek and/or additional clinical trials for AZD4694, RIGScan or other product candidates may not be successful and, even if they are, we may not be successful in developing any of them into a commercial product. In addition, many companies in the pharmaceutical industry suffer significant setbacks in advanced clinical trials even after reporting promising results in earlier trials. Even if our trials are viewed as successful, we may not get regulatory approval. Our product candidates will be successful only if:

- they are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;
- we are able to commercialize them in clinical development or sell the marketing rights to third parties; and
- if developed, they are approved by the regulatory authorities.

We are dependent on the achievement of these goals in order to generate revenues. The failure to generate such revenues may preclude us from continuing our research and development of these and other product candidates.

If we are not successful in licensing or acquiring additional drug candidates or technologies to expand our product pipeline, our future product portfolio and potential profitability could be harmed.

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. All of our product candidates in clinical development are in-licensed from a third-party, including Lymphoseek, AZD4694 and RIGScan. We may not successfully acquire drug

candidates or technologies to expand our product pipeline. The number of such candidates and technologies is limited. Competition among large pharmaceutical companies and biopharmaceutical companies for promising drug candidates and technologies is intense because such companies generally desire to expand their product pipelines through purchase or in-licensing. If we fail to expand our product pipeline, our potential future revenues may be adversely affected.

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 2011, we successfully completed a second Phase 3 clinical trial in subjects with breast cancer or melanoma for our most advanced radiopharmaceutical product candidate, Lymphoseek. In addition, we are enrolling subjects in a third Phase 3 clinical trial in subjects with head and neck squamous cell carcinoma. In August 2011, we also held a meeting with the SAWP of the EMA and received similar guidance as we received from FDA, as well as the suggestion that we consider use of a humanized version of the RIGS antibody. With this collective guidance, we have changed from a murine antibody to a humanized antibody on our development and regulatory timelines. We believe that we may still be technically able to complete the necessary manufacturing steps to permit active clinical development by the end of 2012; however, as management continues to assess the scope and required resources for the RIGS program, particularly in light of other development opportunities such as for AZD4694 and/or [^{123}I]-E-IACFT, the timing and scope of our development and commercialization plan for RIGScan may be affected. With respect to AZD4694, AstraZeneca has completed clinical development through a Phase 2a level. We expect to commence our clinical development through some additional Phase 2 testing, mainly intended to expand the safety population, and to commence Phase 3 testing of AZD4694 in 2013, but these plans could also experience complications and delays.

Historically, the results from preclinical testing and early clinical trials often do not predict the 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, and AstraZeneca achieved successful outcomes from earlier Phase 2 trials of AZD4694, the results of these clinical trials, as well as pending and future trials for these and other product candidates that we may develop or acquire, 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 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 materially harm our business.

If we fail to establish and maintain collaborations or if our partners do not perform, we may be unable to develop and commercialize our product candidates.

We expect to enter into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. Such collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline.

Our dependence on collaborative arrangements with third parties will subject us to a number of risks that could harm our ability to develop and commercialize products including that:

- collaborative arrangements may not be on terms favorable to us;
- disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;
- we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;

- partners may choose to develop, independently or with other companies, alternative products or treatments. including products or treatments which compete with ours;
- agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;
- business combinations or significant changes in a partner's business strategy might adversely affect that partner's willingness or ability to complete its obligations to us; and
- the terms and conditions of the relevant agreements may no longer be suitable.

The occurrence of any of these events could adversely affect the development or commercialization of our products.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations such as health maintenance organizations (HMOs). Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to further reform health care or reduce government insurance programs, may all result in lower prices for our products if approved for commercialization. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to sell our products at a profit.

While we expect a “pass-through” reimbursement code related to Lymphoseek’s designation as a new chemical entity to be established by the U.S. Center for Medicaid and Medicare Services (CMMS) following anticipated FDA approval, there can be no assurance that such pass-through code will be received from CMMS, and if not received, that the cost of Lymphoseek will be absorbed by healthcare providers. In addition, there can be no assurance that, even if a pass-through code is obtained, following the expiration of such code (generally two to three years following approval), we will be successful in establishing a separate permanent code for reimbursement of Lymphoseek and therefore the cost of Lymphoseek may be need to be absorbed by the institution as a part of the bundled procedural code for the surgical procedure in which Lymphoseek is used. If this is the case, our expectations of the pricing we expect to achieve for Lymphoseek and the related potential revenue may be significantly diminished.

We may be unable to establish or contract for the pharmaceutical manufacturing capabilities necessary to develop and commercialize our potential products.

We do not currently own or operate any manufacturing facilities for our 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 have a supply agreement with Reliable Biopharmaceuticals to manufacture the active pharmaceutical ingredient for our Lymphoseek product and are in the process of finalizing a supply contract with a third-party manufacturer for the finishing and vialing of 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, commercialization of Lymphoseek or our clinical trials of other product candidates may be delayed, thereby delaying the submission of product candidates for regulatory approval and their market introduction and subsequent commercialization, if approved. Any such delays may lower our revenues and potential profitability.

We and any third-party manufacturers that we may use must continually adhere to cGMP practices and regulations enforced by FDA through its facilities inspection program and/or foreign regulatory authorities where our products will be tested and/or marketed. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, FDA and/or foreign regulatory authorities will not grant approval to market 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. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. Failure to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

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

The biotechnology industry is intensely competitive. Some of our competitors have significantly greater financial, technical, manufacturing, marketing and distribution resources as well as greater experience in the pharmaceutical industry than we have. The particular medical conditions our product lines address can also be addressed by other medical procedures or drugs. Many of these alternatives are widely accepted by physicians and have a long history of use. For example, recently, a competitor announced that it had received approval to modify the product labeling for sulfur colloid, a product that competes with our Lymphoseek drug, in the identification of lymph nodes in breast cancer patients. 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 may not occur at the rate we anticipate or may decline. In addition, our current and potential competitors may establish cooperative relationships with larger 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.

If any of our license agreements for intellectual property underlying Lymphoseek, AZD4694 or RIGScan, or any other products or potential products are terminated, we may lose the right to develop or market that product.

We have licensed intellectual property, including patents and patent applications relating to intellectual property for Lymphoseek, AZD4694 and RIGScan. We have also entered into an option agreement to license [I^{123}]-E-IACFT and may enter into other license agreements or acquire other product candidates. The potential success of our product development programs depend on our ability to maintain rights under these licenses, including our ability to achieve development or commercialization milestones contained in the licenses. Under certain circumstances, the licensors have the power to terminate its agreement with us if we fail to meet our obligations under these licenses. We may not be able to meet our obligations under these licenses. If we default under any license agreement, we may lose our right to market and sell any products based on the licensed technology.

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 for our products and product candidates, to preserve our trade secrets, and to operate without infringing on the proprietary rights 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.

Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. As the biotechnology and pharmaceutical industry expands and more patents are issued, the risk increases that we will be subject to claims that our products or product candidates, or their use, infringe the rights of others. 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, limit our patents, invalidate our patent applications or create a risk of infringement claims.

We or our suppliers may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products, product candidates and/or technologies infringe their intellectual property rights or that the process of manufacturing our products or any of their respective component materials, or the component materials themselves, or the use of our products, product candidates or technologies, infringe their intellectual property rights. If one of these patents was found to cover our products, product candidates, technologies or their uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our products or use our technologies or methods unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, if at all. In addition, during litigation, a patent holder could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using or selling our products, technologies or methods.

In addition, it may be necessary for us to enforce patents under which we have rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, which may affect our rights. There can be no assurance that our patents would be held valid by a court or administrative body or that an alleged infringer would be found to be infringing. The uncertainty resulting from the mere institution and continuation of any patent related litigation or interference proceeding could have a material and adverse effect on us.

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 and our collaborators, including AstraZeneca, may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates and products, when and if we have any, in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products. These products may compete with our products, when and if we have any, and may not be covered by any of our or our licensors' patent claims or other intellectual property rights.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

The intellectual property protection for our product candidates depends on third parties.

With respect to Lymphoseek, AZD4694 and RIGScan, we have exclusively licensed certain issued patents and pending patent applications covering the respective technologies underlying these product candidates and their commercialization and use and we have licensed certain issued patents and pending patent applications directed to product compositions and chemical modifications used in product candidates for commercialization, and the use and the manufacturing thereof.

The patents and pending patent applications underlying our licenses do not cover all potential product candidates, modifications and uses. In the case of patents and patent applications licensed from AstraZeneca, we have limited control over the filing, prosecution or enforcement of these patents or patent applications. In the case of patents and patent applications licensed from UCSD, we did not have any control over the filing of the patents and patent applications before the effective date of the Lymphoseek license, and have had limited control over the filing and prosecution of these patents and patent applications after the effective date of the Lymphoseek license. Under certain circumstances, we also have the right to enforce patents and patent applications licensed from AstraZeneca. We cannot be certain that such prosecution efforts have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. We also cannot be assured that our licensors or their respective licensing partners will agree to enforce any such patent rights at our request or devote sufficient efforts to attain a desirable result. Any failure by our licensors or any of their respective licensing partners to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operation.

We may become involved in disputes with AstraZeneca, UCSD, the National Institutes of Health (NIH) or potential future collaborators over intellectual property ownership, and publications by our research collaborators and scientific advisors could impair our ability to obtain patent protection or protect our proprietary information, which, in either case, could have a significant effect on our business.

Inventions discovered under research, material transfer or other such collaborative agreements, may become jointly owned by us and the other party to such agreements in some cases and the exclusive property of either party in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention, or whether it is jointly owned, and disputes could arise regarding ownership of those inventions. These disputes could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect or license rights to these inventions. In addition, our research collaborators and scientific advisors generally have contractual rights to publish our data and other proprietary information, subject to our prior review. Publications by our research collaborators and scientific advisors containing such information, either with our permission or in contravention of the terms of their agreements with us, may impair our ability to obtain patent protection or protect our proprietary information, which could significantly harm our business.

We may have difficulty raising additional capital, which could deprive us of necessary resources to pursue our business plans.

We expect to devote significant capital resources to fund research and development, to maintain existing and secure new manufacturing capacity, and to acquire new product candidates. 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.

Our future expenditures on our programs are subject to many uncertainties, including whether our product candidates will be developed or commercialized with a partner or independently. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of seeking regulatory approval for our product candidates, including any nonclinical testing or bioequivalence or clinical studies, process development, scale-up and other manufacturing and stability activities, or other work required to achieve such approval, as well as the timing of such activities and approval;
- the extent to which we invest in or acquire new technologies, product candidates, products or businesses and the development requirements with respect to any acquired programs;
- the scope, prioritization and number of development and/or commercialization programs we pursue and the rate of progress and costs with respect to such programs;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities and regulatory compliance capabilities, if we commercialize any of our product candidates for which we obtain regulatory approval without a partner;
- the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;
- the extent to which we will need to expand our workforce to pursue our business plan, and the costs involved in recruiting, training and incentivizing new employees;
- the effect of competing technological and market developments; and
- the cost involved in establishing, enforcing or defending patent claims and other intellectual property rights.

We believe that we have access to sufficient financial resources with which to fund our operations and those of our subsidiaries for the foreseeable future. However, certain events or actions may shorten the period through which our current operating funds will sustain us, including, without limitation, if we decide to grow our organization in pursuit of development or commercialization activities for our current or newly acquired or developed product candidates, if we incur unexpected expenses, or if FDA approval of Lymphoseek is significantly delayed. We may also acquire new technologies, product candidates and/or products and the cost to acquire, develop and/or commercialize such new technologies, product candidates and/or products may shorten the period through which our current operating funds will sustain us. If our current funds become inadequate, we may not be able to obtain sufficient additional funding for such activities, on satisfactory terms, if at all. If we are unsuccessful in raising additional capital, 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, acquisition of new product candidates and other operations.

Our ability to raise capital may be limited by applicable laws and regulations.

Our ability to raise additional capital through the sale and issuance of our equity securities may be limited by, among other things, current Securities and Exchange Commission (Commission) and NYSE Amex Equities exchange (NYSE Amex) rules and regulations. Our capital raising plans include primary offerings of equity securities using a “shelf” registration on Form S-3, which typically enables an issuer to raise additional capital on a more timely and cost effective basis than through other means, such as registration of a securities offering under a Form S-1 registration statement. Under current Commission rules and regulations, to be eligible to use a Form S-3 registration statement for primary offerings without restriction as to the amount of securities to be sold and issued, an issuer must, among other requirements, have outstanding common equity with a market value of at least $75 million held by non-affiliates. Although we currently have outstanding common equity with a market value of significantly more than $75 million held by non-affiliates, if we file a “shelf” Form S-3 registration statement at a time when the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75 million (calculated as set forth in Form S-3 and Commission rules and regulations), the amount we could raise through primary offerings of our securities in any 12-month period using the Form S-3 registration statement may be limited to an aggregate of one-third of our public

float. Moreover, the market value of all securities sold by us under a Form S-3 registration statement during the prior 12 months may be subtracted from that amount to determine the amount we can then raise under the Form S-3 registration statement. The Commission's rules and regulations require that we periodically re-evaluate the value of our public float. If, at a re-evaluation date, our public float is less than $75 million, the amount we could raise through primary offerings of our securities in any 12-month period using a Form S-3 registration statement would be subject to the one-third of public float limitation described above.

In addition, under current Commission rules and regulations, if our public float is less than $75 million or if we seek to register a resale offering (i.e., an offering of our securities by persons other than us), we must, among other requirements, maintain our listing with the NYSE Amex or have our common stock listed and registered on another national securities exchange in order to be eligible to use a Form S-3 registration statement for any primary or resale offering. Alternative means of raising capital through sales of our securities, including through the use of a Form S-1 registration statement, may be more costly and time-consuming.

Currently, our common stock is listed on the NYSE Amex. The NYSE Amex will review the appropriateness of continued listing of any issuer that falls below the exchange's continued listing standards. For additional information regarding this risk, see the risk factor below titled "Our failure to maintain continued compliance with the listing requirements of the NYSE Amex could result in the delisting of our common stock." If our common stock were delisted from the NYSE Amex, our ability to raise capital on terms and conditions we deem acceptable, if at all, may be materially impaired.

Our ability to timely raise sufficient additional capital also may be limited by the NYSE Amex's requirements relating to stockholder approval for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, the NYSE Amex requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our presently outstanding common stock, unless the transaction is considered a "public offering" by the NYSE Amex staff. Based on our outstanding common stock as of February 17, 2012 and the average closing price of $2.97 over the thirty days preceding February 17, 2012, we could not raise more than approximately $55 million without stockholder approval, unless the transaction is deemed a public offering or does not involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. However, certain prior sales by us may be aggregated with any offering we may propose in the near-term, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE Amex staff and would involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. The NYSE Amex will also require stockholder approval if the issuance or potential issuance of additional shares will be considered by the exchange staff to result in a change of control of Navidea.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our current business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction. A public offering under the NYSE Amex rules typically involves broadly announcing the proposed transaction, which often times has the effect of depressing the issuer's stock price. Accordingly, the price at which we could sell our securities in a public offering may be less and the dilution existing stockholders experience may in turn be greater than if we were able to raise capital through other means.

There may be future sales or other dilution of our equity, which may adversely affect the market price of shares of our common stock.

Our existing and future preferred stock, warrants or other securities convertible into or exchangeable for our common stock may contain adjustment provisions that could increase the number of shares issuable upon exercise, conversion or exchange, as the case may be, and decrease the exercise, conversion or exchange price. The market price of our shares of common stock or preferred stock could decline as a result of sales of a large number of shares of our common stock or preferred stock or similar securities in the market, the triggering of any such adjustment provisions or the perception that such sales could occur in the future.

Our secured indebtedness imposes significant restrictions on us, and a default could materially adversely affect our operations and financial condition.

All of our material assets, except our intellectual property, have been pledged as collateral for our borrowings under the Loan and Security Agreement (Loan Agreement) with Hercules Technology II. LP (Hercules). In addition to the security interest in our assets, the Loan Agreement carries substantial covenants that impose significant requirements on us, including, among others, requirements that:

- we pay all principal, interest and other charges on the borrowed funds when due;
- we keep reserved out of our authorized shares of common stock sufficient shares to satisfy our obligation to issue shares on conversion of the debt and the exercise of the warrants issued in connection with the Loan Agreement; and
- we indemnify Hercules against certain liabilities.

Additionally, with certain exceptions, the Loan Agreement prohibits us from:

- amending our organizational or governing agreements and documents, entering into any merger or consolidation, dissolving the Company or liquidating its assets, or acquiring all or any substantial part of the business or assets of any other person;
- incurring any indebtedness, capital leases, or contingent obligations outside the ordinary course of business;
- granting or permitting liens against or security interests in our assets;
- acquiring or making investments in any other person other than permitted investments;
- making any material dispositions of our assets outside the ordinary course of business; or
- declaring or paying any dividends or making any other distributions.

Our ability to comply with these provisions may be affected by changes in our business condition or results of our operations, or other events beyond our control. The breach of any of these covenants would result in a default under the Loan Agreement, permitting Hercules to accelerate the maturity of the debt and to sell the assets securing it. Such actions by Hercules could materially adversely affect our operations, results of operations and financial condition, including causing us to substantially curtail our product development activities.

Shares of common stock are equity securities and are subordinate to our existing and future indebtedness and preferred stock.

Shares of our common stock are common equity interests. This means that our common stock ranks junior to our outstanding shares of Series B and Series C Preferred Stock and any preferred stock that we may issue in the future, to our indebtedness and to all creditor claims and other non-equity claims against us and our assets available to satisfy

claims on us, including claims in a bankruptcy or similar proceeding. Our existing and future indebtedness and our preferred stock may restrict payment of dividends on our common stock.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our Board of Directors or a duly authorized committee of our Board of Directors, and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to shareholders generally.

The global financial crisis may have an impact on our business and financial condition in ways that we currently cannot predict, and may further limit our ability to raise additional funds.

The ongoing credit crisis and related turmoil in the global financial system has had and may continue to have an impact on our business and our financial condition. We may face significant challenges if conditions in the financial markets do not improve or continue to worsen. In particular, our ability to access the capital markets and raise funds required for our operations may be severely restricted at a time when we would like, or need, to do so which could have an adverse effect on our ability to meet our current and future funding requirements and on our flexibility to react to changing economic and business conditions.

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 is listed on the NYSE Amex, having recently been listed in February 2011. The rules of NYSE Amex 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 NYSE Amex 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. For example, the NYSE Amex normally will consider suspending trading in, or removing from the list, securities of an issuer that has stockholders' equity of less than $6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. There can be no assurance that the Company will continue to meet these and other requirements necessary to maintain the listing of our common stock on the NYSE Amex. For example, we may determine to grow our organization or product pipeline or pursue development or other activities at levels or on timelines that reduces our stockholders' equity below the level required to maintain compliance with NYSE Amex continued listing standards.

The delisting of our common stock from the NYSE Amex likely would reduce the trading volume and liquidity in our common stock and may lead to decreases in the trading price of our common stock. The delisting of our common stock may also materially impair our stockholders' ability to buy and sell shares of our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital, which is critical to the execution of our current business strategy.

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 $1.62 per share and as high as $5.48 per share during the 12-month period ended February 17, 2012. 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 or of companies in our industry which do not relate to our operating performance;
- changes in securities analysts' estimates of our financial performance or deviations in our business and the trading price of our common stock from the estimates of securities analysts;
- FDA or international regulatory actions and regulatory developments in the U.S. and foreign countries;

- 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;
- activities of short sellers in our stock; and
- fluctuations in market demand for and supply of our products.

The realization of any of the foregoing could have a dramatic and adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced substantial decline in market price. Moreover, regulatory entities often undertake investigations of investor transactions in securities that experience volatility following an announcement of a significant event or condition. Any such litigation brought against us or any such investigation involving our investors could result in substantial costs and a diversion of management's attention and resources, which could hurt our business, operating results and financial condition.

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 NYSE Amex on February 10, 2011, trading in our common stock has been more active; during the period beginning on February 10, 2011 and ending on February 17, 2012, the average daily trading volume for our common stock on the NYSE Amex was approximately 900,000 shares. We cannot, however, assure you that this trading volume will be consistently maintained in the future.

The market price of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on the NYSE Amex Equities exchange.

The market price of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on the NYSE Amex. These conditions may result in (i) volatility in the level of, and fluctuations in, the market prices of stocks generally and, in turn, our shares of common stock, and (ii) sales of substantial amounts of our common stock in the market, in each case that could be unrelated or disproportionate to changes in our operating performance.

Because we do not expect to pay dividends on our common stock in the foreseeable future, stockholders will only benefit from owning common stock if it appreciates.

We have paid no cash dividends on any of our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, with respect to our common stock, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we are subject to various laws and regulations that may restrict our ability to pay dividends and we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Due to our intent to retain any future earnings rather than pay cash dividends on our common stock and applicable laws, regulations and contractual obligations that may restrict our ability to pay dividends on our common stock, the success of your investment in our common stock will likely depend entirely upon any future appreciation and there is no guarantee that our common stock will appreciate in value.

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 development initiatives. Our management will need to remain flexible to support our business model over the next few years. However, losing members of the Navidea 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 pharmaceutical industry, and the acquisition of additional product candidates may require us to acquire additional highly qualified personnel. 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.

If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.

If appropriate opportunities become available, we may attempt to acquire businesses and assets that we believe are a strategic fit with our business. We currently have no agreements to consummate any material acquisitions. If we pursue any such transaction, the process of negotiating the acquisition and integrating an acquired business and assets may result in operating difficulties and expenditures and may require significant management attention that would otherwise be available for ongoing development of our business whether or not any such transaction is ever consummated. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets which could harm our business, financial condition, operating results and prospects and the trading price of our securities.

We may be adversely affected if our controls over external financial reporting fail or are circumvented.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes Oxley Act of 2002 to report annually on our internal control over financial reporting. If it were to be determined that our internal control over financial reporting is not effective, such shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could

result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively affect the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The effect of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors and our Board committees and as executive officers.

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 development activities depending on the level of activities performed internally versus by third parties.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosure

Not applicable.

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 NAVB. Prior to our name change from Neoprobe Corporation to Navidea Biopharmaceuticals, Inc. on January 5, 2012, our common stock was traded 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
Fiscal Year 2011:		
First Quarter	$4.71	$2.00
Second Quarter	5.48	3.05
Third Quarter	3.60	1.62
Fourth Quarter	3.18	2.05
Fiscal Year 2010:		
First Quarter	$2.30	$1.15
Second Quarter	2.00	1.50
Third Quarter	2.15	1.66
Fourth Quarter	2.32	1.50

As of February 17, 2012, we had approximately 724 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.

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Stock Performance Graph

The following graph compares the cumulative total return on a $100 investment in each of the common stock of the Company, the Russell 3000, and the NASDAQ Biotechnology Index for the period from December 31, 2006 through December 31, 2011. This graph assumes an investment in the Company's common stock and the indices of $100 on January 1, 2006 and that all dividends were reinvested.

	Cumulative Total Return as of December 31,					
	2006	2007	2008	2009	2010	2011
Navidea Biopharmaceuticals	$100.00	$119.17	$237.50	$508.33	$858.33	$1,091.67
Russell 3000	100.00	105.14	65.92	84.60	98.92	99.93
NASDAQ Biotechnology	100.00	102.53	96.57	110.05	117.19	124.54

Item 6. Selected Financial Data

The following summary financial data are derived from our consolidated financial statements that have been audited by our independent registered public accounting firm. These data are qualified in their entirety by, and should be read in conjunction with, our Consolidated Financial Statements and Notes thereto included elsewhere in this Form 10-K as well as Management's Discussion and Analysis of Financial Condition and Results of Operations. Summary financial data for 2011 and prior periods reflect the disposition of our gamma detection device business (GDS Business) in August 2011 and the reclassification of certain related items to discontinued operations.

(Amounts in thousands, except per share data)	Years Ended December 31,				
	2011	2010	2009	2008	2007
Statement of Operations Data:					
Grant revenue	$598	$617	$—	$—	$—
Research and development expenses	15,154	8,941	4,380	3,756	2,116
Selling, general and administrative expenses	9,548	4,353	3,028	2,936	2,388
Loss from operations	(24,104)	(12,677)	(7,408)	(6,692)	(4,504)
Other expenses, net	(943)	(43,567)	(35,891)	(2,124)	(3,325)
Benefit from income taxes	7,880	2,135	1,256	1,241	932
Loss from continuing operations	(17,167)	(54,109)	(42,043)	(7,575)	(6,897)
Discontinued operations, net of tax effect	22,780	4,144	2,437	2,409	1,809
Net income (loss)	5,613	(49,965)	(39,606)	(5,166)	(5,088)
Preferred stock dividends	(100)	(8,207)	(240)	—	—
Income (loss) attributable to common stockholders	$5,513	$(58,172)	$(39,846)	$(5,166)	$(5,088)
Income (loss) per common share (basic and diluted):					
Continuing operations	$(0.17)	$(0.77)	$(0.57)	$(0.12)	$(0.11)
Discontinued operations	$0.23	$0.05	$0.03	$0.04	$0.03
Income (loss) attributable to common stockholders	$0.06	$(0.72)	$(0.54)	$(0.08)	$(0.08)
Shares used in computing income (loss) per common share: [1]					
Basic and diluted	90,509	80,726	73,772	68,594	62,921

	As of December 31,				
	2011	2010	2009	2008	2007
Balance Sheet Data:					
Total assets	$31,194	$10,863	$9,018	$9,619	$7,063
Long-term obligations	6,714	2,787	13,485	7,323	8,836
Accumulated deficit	(245,357)	(250,870)	(192,699)	(148,840)	(140,777)

(1) Basic earnings (loss) per share is calculated by dividing net income (loss) by the weighted-average number of common shares and, except for periods of loss, participating securities outstanding during the period. Diluted earnings (loss) per share reflects additional common shares that would have been outstanding if dilutive potential common shares had been issued. Potential common shares that may be issued by the Company include convertible securities, options and warrants.

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

Navidea Biopharmaceuticals, Inc. (formerly Neoprobe Corporation; Navidea, the Company, or we), a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. We are currently developing three radiopharmaceutical agent platforms. The first, Lymphoseek® (Tilmanocept), is intended to be used in determining the spread of certain solid tumor cancers into the lymphatic system. The second, AZD4694, is intended to aid in the imaging and evaluation of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD). The third, RIGScan™, is intended to be used during surgery to help surgeons locate occult or metastatic cancer, with a primary focus on colorectal cancer. All of these drug products are still in development and must be cleared for marketing by the appropriate regulatory bodies before they can be sold in any markets.

Executive Summary

We believe that the future prospects for Navidea continue to improve as we make progress in executing our strategic vision to become a leader in precision diagnostics. Our primary development efforts over the last few years have been focused on the development of our two radiopharmaceutical platforms within oncology, Lymphoseek and RIGScan. We expect our overall research and development expenditures to continue to be significantly higher during 2012 as compared to 2011 due to the expansion of our clinical, regulatory, and business development staff and efforts that support the commercialization of Lymphoseek, further development of RIGScan, and development of additional radiopharmaceutical pipeline product candidates, including our most recent addition, AZD4694. The level to which the expenditures rise will depend on the extent to which we are able to execute on these strategic initiatives.

Our efforts in 2011 and to date in 2012 have resulted in the following milestone achievements:

Corporate/Financial

- Achieved listing of our common stock on the NYSE Amex Stock Exchange
- Secured independent analyst coverage from several major brokerage firms
- Appointed Dr. Mark Pykett as President and Chief Executive Officer, and appointed Drs. Peter Drake, Jess Jones and Mark Pykett to the Navidea Board of Directors
- Filed a shelf registration on Form S-3 to allow the Company to raise capital as necessary through the sale of up to $100 million in a primary offering of securities
- Appointed Dr. Thomas Tulip as Executive Vice President and Chief Business Officer
- Completed the sale of our GDS Business to Devicor Medical Products, Inc., for $30.2 million in proceeds and up to an additional $20 million in potential future royalties
- Established a European business unit to support regulatory, development and commercial activities in the European Union (EU)
- Executed a Loan Agreement with Hercules Technology II, L.P. providing for a first advance of $7 million which was received in December 2011, and the availability of a second advance of an additional $3 million, subject to certain milestone conditions
- Completed strategic repositioning and rebranding activities of the Company as a pure-play radiopharmaceutical developer
- Completed a lease agreement for additional office space in Andover, Massachusetts to house the Company’s business development and commercialization team

Pipeline

- Announced that our second clinical study of Lymphoseek in subjects with breast cancer or melanoma (NEO3-09) reached its accrual goal
- Announced top-line data from the NEO3-09 clinical study with all primary and secondary endpoints achieved and presented full data from the study at major medical meetings
- Presented full data from the NEO3-09 clinical study at the American Society of Clinical Oncology and Society of Nuclear Medicine Meetings
- Obtained positive guidance from the European Medicines Agency (EMA) for Lymphoseek and announced our intent to file a Marketing Authorization Application (MAA) in the EU by the end of 2012 based on already completed clinical trials
- Executed a license agreement with AstraZeneca AB for the exclusive worldwide license of AZD4694, a proprietary compound intended for use in diagnosing Alzheimer's Disease
- Completed a successful pre-investigational new drug meeting for RIGScan with the U.S. Food and drug Administration (FDA)
- Undertook process development and pilot production activities for RIGScan manufacturing
- Filed and received notice of the acceptance of the Lymphoseek New Drug Application (NDA) from FDA
- Completed a scientific advice meeting with the EMA for RIGScan development in the EU
- Entered into an option agreement with Alseres Pharmaceuticals, Inc. to license [^{123}I]-E-IACFT Injection, also called Altropane®, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and movement disorders

Our Outlook

Excluding the results of our discontinued operations, as discussed below, our operating expenses over the last three years have been focused primarily on support of Lymphoseek product development, and to a lesser extent, on efforts to restart active development of RIGScan. In addition, in December 2011, we paid a $5 million up-front fee upon execution of a license agreement with AstraZeneca for the exclusive worldwide license of AZD4694.

We spent approximately $15.2 million, $8.9 million and $4.4 million in total on research and development activities in the years ended December 31, 2011, 2010 and 2009, respectively. Following the sale of the GDS Business, our entire organization is focused on the development of radiopharmaceutical agents that fulfill our vision of becoming a leader in precision diagnostics. Of the total amounts we have spent on research and development over the last three years, excluding costs related to our internal research and development headcount and our general and administrative staff which we currently do not allocate among the various development programs that we have underway, we incurred out-of-pocket charges by program as follows:

Development Program	2011	2010	2009
Lymphoseek	$5,286,395	$5,854,703	$2,854,819
AZD4694	5,018,490	—	—

RIGScan	1,302,851	940,435	83,628

We expect our drug-related development and commercialization expenses to increase significantly in 2012 over 2011.

With respect to Lymphoseek, we were notified by FDA that the Prescription Drug User Fee Act (PDUFA) date for Lymphoseek is June 10, 2012. Depending on the timing and outcome of the FDA regulatory review cycle, we believe that Lymphoseek can be commercially launched in the second half of 2012. During 2012, we expect to incur additional development expenses related to supporting the NDA review of Lymphoseek, our preparation to file an MAA in the EU, the completion of our NEO3-06 clinical trial and potentially studies to support Lymphoseek in a post-commercialization setting and support the other product activities related to the potential marketing registration of Lymphoseek in the U.S. and other markets. In addition, we expect to incur significant costs during 2012 to support our business development and commercialization activities surrounding Lymphoseek.

Following the licensing of AZD4694, we expect to incur significant expenses during 2012 related to preparing for the commencement of additional Phase 2 clinical trials in 2012 and preparing for a pivotal Phase 3 clinical trial in 2013, as well costs for manufacturing-related activities required prior to filing for regulatory clearance to market. AZD4694 is currently not expected to contribute any revenue to the Company until 2016.

We are also moving forward with manufacturing activities to support further development of RIGScan. We believe that we may still be technically able to complete the necessary manufacturing steps to permit active clinical development of RIGScan by the end of 2012; however, as management continues to assess the scope and required resources for the RIGS® program, particularly in light of other development opportunities such as for AZD4694 and our option to license [^{123}I]-E-IACFT, the timing and scope of our development and commercialization plan for RIGScan may be affected. We continue to believe it may be advantageous for us to identify a development partner for RIGScan. We have engaged in discussions with various parties over the past few years regarding potential partnerships and/or other development arrangements. 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.

Finally, if we choose to exercise our option to license [^{123}I]-E-IACFT Injection and are successful in completing a definitive license, or if we are successful in identifying and securing additional product candidates to augment our product development pipeline, we will likely incur significant additional expenses related to furthering the development of such products.

Discontinued Operations

From our inception through August 2011, we developed and marketed a line of medical devices, the neoprobe® GDS gamma detection systems (the GDS Business). However, following an analysis of our strategic goals and objectives, our Board of Directors authorized, and on May 24, 2011, we executed, an Asset Purchase Agreement (APA) to sell our gamma detection device line of business (the Asset Sale) to Devicor Medical Products, Inc. (Devicor). Our shareholders approved the Asset Sale on August 15, 2011 and the sale closed on August 17, 2011 consistent with the

terms of the APA. Under the terms of the APA, we sold the assets and assigned certain liabilities that were primarily related to the GDS Business. In exchange for the assets of the GDS Business, Devicor made cash payments to us of $30.3 million, assumed certain liabilities of the Company associated with the GDS Business, and agreed to make royalty payments to us of up to an aggregate maximum amount of $20 million based on the net revenue attributable to the GDS Business over the course of the next six fiscal years starting with 2012. In December 2011, we entered an agreement to transfer potential liability related to extended warranty contracts related to the GDS Business, which were outstanding as of the date of the sale of the GDS Business but which were not included in the August 2011 transaction. In exchange for transferring the liability related to the extended warranty contracts to Devicor, we made a cash payment to Devicor of $178,000. Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the GDS Business as a discontinued operation. Cash flows associated with the operation of the GDS Business have been combined within operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows.

In August 2009, the Company's Board of Directors decided to discontinue the operations and attempt to sell our wholly owned subsidiary, Cardiosonix Ltd. (Cardiosonix). 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 part to positive achievements related to our other device product and drug development initiatives. We have not received significant expressions of interest in the Cardiosonix business; however, we are obligated to continue to service and support the Cardiosonix devices through 2013. As such, while we continue to wind down our activities in this area, we expect to continue to generate minimal revenues and incur minimal expenses related to our blood flow measurement device business until a final shutdown of operations or a sale of the business unit is completed. Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the blood flow measurement device segment as a discontinued operation. Cash flows associated with the operation of the blood flow measurement device segment have been combined within operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows.

Results of Operations

This discussion of our Results of Operations focuses on describing results of our operations as if we had not operated the discontinued operations discussed above during the periods being disclosed. In addition, since our radiopharmaceuticals are not yet generating commercial revenue, the discussion of our revenue focuses on the grant revenue we have received and our operating variances focus on our radiopharmaceutical development programs and the supporting general and administrative expenses.

With respect to our grant revenue, in June 2010, Navidea 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 was used to accelerate the application of Lymphoseek in head and neck cancer treatment and involved a collaboration of several Ohio-based companies as well as leading cancer centers in the U.S. Navidea and its collaborators were required to contribute an additional $1.1 million in matching funds over the course of the project. We recognized Ohio Third Frontier grant revenue of approximately $592,000 and $358,000 during 2011 and 2010, respectively, and expect to recognize the remaining $50,000 as revenue during 2012. In October 2010, Navidea 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 Navidea. We recognized the entire $244,000 of QTDP grant revenue in the fourth quarter of 2010. During 2011 and 2010, Navidea received and recognized an additional $6,000 and $15,000, respectively, of miscellaneous grant revenue.

Years Ended December 31, 2011 and 2010

Grant Revenue. Grant revenue, primarily related to the Ohio Third Frontier grant to support Lymphoseek development, was $598,000 during 2011. Grant revenue of $617,000 during 2010 was primarily related to the Ohio

Third Frontier and QTDP grants.

Research and Development Expenses. Research and development expenses increased $6.3 million, or 70%, to $15.2 million during 2011 from $8.9 million in 2010. The increase was primarily due to net increases in drug project expenses related primarily to (i) the $5.0 million initial license fee for AZD4694, (ii) increased Lymphoseek development costs including the $1.5 million filing fee for the Lymphoseek NDA, regulatory consulting costs of $452,000, and license fees of $70,000, (iii) increased manufacturing, and regulatory project costs of $457,000 related to RIGScan, and (iv) project costs of $355,000 related to various potential new product candidates; offset by decreases in drug project expenses of (v) decreased process development costs of $1.7 million and decreased clinical activity costs of $956,000 related to Lymphoseek, and (vi) decreased process development costs of $76,000 related to RIGScan. The net increase in research and development expenses was also due to increased compensation of $914,000 due to increased headcount required for expanded development efforts and increased related expenses such as incentive-based compensation, travel and supplies.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $5.1 million, or 119%, to $9.5 million during 2011 from $4.4 million in 2010. The net increase was primarily due to separation costs of $2.3 million related to the separation of our former President and CEO, David Bupp; increased compensation costs of $1.4 million related to net increased headcount and incentive-based compensation; increased professional services and consulting costs of $850,000 that supported preparation for Lymphoseek commercialization, listing on the NYSE Amex, and various corporate governance and investor relations issues; and increased Board of Directors costs of $217,000 due to increased meeting fees related to the number of transactions considered during 2011 and stock-based incentive compensation. The net increase in selling, general and administrative expenses was also due to increased headcount-related costs such as travel, recruiting and space costs.

Other Income (Expense). Other expense, net decreased $42.6 million to $943,000 in 2011 from $43.6 million in 2010. 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 2011 and 2010, we recorded charges of $952,000 and $1.3 million, respectively, related to the increases in derivative liabilities resulting from the requirement to mark our derivative liabilities to market. Interest expense decreased $542,000 to $13,000 during 2011 from $555,000 in 2010, primarily due to the June 2010 exchange of our then-outstanding convertible debt agreements for convertible preferred stock. Of this interest expense, $403,000 in 2010 was non-cash in nature due to the payment or accrued payment of interest on our convertible debt with shares of our common stock. In addition, $4,000 and $16,000 of interest expense during 2011 and 2010, respectively, was non-cash in nature related to the amortization of debt discounts and issuance costs resulting from warrants and conversion features related to our convertible debt. Interest income increased $17,000 to $26,000 during 2011 from $9,000 in 2010, primarily due to increased cash balances.

Income Taxes. Estimated tax liabilities of $6.7 million related to the gain on the sale of discontinued operations and $1.2 million related to income from discontinued operations were fully offset by an estimated tax benefit of $7.9 million related to the loss from continuing operations during 2011. Estimated tax liabilities of $2.1 million related to income from discontinued operations were fully offset by an estimated tax benefit of $2.1 million related to the loss from continuing operations during 2010.

Gain on Sale of Discontinued Operations. We recognized a gain on sale of discontinued operations related to the sale of our GDS Business to Devicor and subsequent disposition of our extended warranty contracts of $19.5 million during 2011. The sales price of $30.3 million was offset by a cash payment to Devicor of $178,000 in exchange for transferring the liability related to the extended warranty contracts, $2.8 million in investment banking, legal and other fees related to the sale, $1.2 million in net balance sheet dispositions and write-offs, and $6.7 million in estimated taxes which were allocated to discontinued operations, but were fully offset by the tax benefit from our net operating loss for 2011.

Income from Discontinued Operations. Income from discontinued operations decreased $815,000, or 20%, to $3.3 million during 2011 from $4.1 million in 2010, primarily due to the sale of our GDS Business to Devicor in August 2011. Total revenues from discontinued operations were $7.7 million and $10.1 million in 2011 and 2010, respectively.

Years Ended December 31, 2010 and 2009

Grant Revenue. Grant revenue, primarily related to the Ohio Third Frontier grant to support Lymphoseek development and the QTDP grant, was $617,000 during 2010. Recognition of grant revenue began late in the third quarter of 2010.

Research and Development Expenses. Research and development expenses increased $4.5 million, or 104%, to $8.9 million during 2010 from $4.4 million in 2009. The net increase was primarily due to (i) increased process development costs of $1.5 million, increased clinical activity costs of $929,000, increased regulatory consulting costs of $303,000, and increased pricing study costs of $217,000, all related to Lymphoseek, (ii) increased process development costs of $544,000, increased regulatory consulting costs of $118,000, increased pricing study costs of $108,000, and increased license fees of $62,000, all related to RIGScan, and (iii) increased compensation costs of $680,000 related to increased headcount and incentive-based compensation.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $1.4 million, or 44%, to $4.4 million during 2010 from $3.0 million in 2009. The increase was primarily due to increased financial advisory fees of $304,000, increased compensation costs of $254,000 related to increased headcount and incentive-based compensation, increased investor relations fees of $225,000 related to re-listing the Company's stock on a major exchange, increased Board of Directors costs of $162,000 related to increased incentive-based compensation and fees, increased professional services of $152,000, 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.

Income Taxes. Estimated tax liabilities of $2.1 million related to income from discontinued operations were fully offset by an estimated tax benefit of $2.1 million related to the loss from continuing operations during 2010. An estimated tax benefit of $583,000 related to the impairment loss for discontinued operations and estimated tax liabilities of $1.8 million related to income from discontinued operations were fully offset by an estimated tax benefit of $1.3 million related to the loss from continuing operations during 2009.

Impairment Loss on 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. As a result, we recorded an impairment loss for discontinued operations of $1.1 million, net of the related tax benefit of $583,000, for the year ended December 31, 2009.

Income from Discontinued Operations. Income from discontinued operations increased $576,000, or 16%, to $4.1 million during 2010 from $3.6 million in 2009, primarily due to increased sales of our gamma detection device products. Total revenues from discontinued operations were $10.1 million and $9.6 million in 2010 and 2009, respectively.

Liquidity and Capital Resources

Cash balances increased to $28.6 million at December 31, 2011 from $6.4 million at December 31, 2010. The net increase was primarily due to $27.3 million of net cash received for the sale of the GDS Business and disposition of the related extended warranty contracts, $6.8 million of net cash received upon completion of a convertible debt agreement, and $4.4 million for the exercise of warrants and stock options, net of $2.8 million paid for related tax withholdings primarily related to the separation of our former President and CEO, David Bupp, partially offset by cash used to fund our operations, mainly for research and development activities. The current ratio increased to 9.0:1 at December 31, 2011 from 2.6:1 at December 31, 2010.

Operating Activities. Cash used in operations increased $10.8 million to $16.0 million during 2011 compared to $5.2 million during 2010. Cash used in operations increased $3.7 million to $5.2 million during 2010 compared to $1.5 million during 2009.

Accounts receivable decreased to $16,000 at December 31, 2011 from $138,000 at December 31, 2010. The balance reflects fluctuations in grant revenue receivable from the State of Ohio. We expect receivables balances to remain low during the first half of 2012 as we have only $50,000 of the $1.0 million Third Frontier grant remaining to recognize, which we will not be able to do until the development project being funded by the grant is complete and the required final reports have been filed. We expect receivables balances to increase significantly following the commercial launch of Lymphoseek.

Inventory levels increased to $821,000 at December 31, 2011 from $632,000 at December 31, 2010 related to the finishing and vialing of a new lot of Lymphoseek, offset by some usage for research and development. Inventory levels increased to $632,000 at December 31, 2010 from $525,000 at December 31, 2009. 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 our inventory levels to increase over the coming months as we manufacture additional product in preparation for commercial launch of Lymphoseek.

Prepaid expenses and other current assets increased to $555,000 at December 31, 2011 from $258,000 at December 31, 2010, primarily due to the income tax receivable related to the overpayment of estimated 2011 taxes due to the estimated gain on the Asset Sale and increased insurance premiums paid during the fourth quarter of 2011. Prepaid expenses and other current assets decreased to $258,000 at December 31, 2010 from $474,000 at December 31, 2009, primarily due to the reclassification of deferred stock offering costs to additional paid-in capital related to the issuance of common stock.

Accounts payable decreased to $682,000 at December 31, 2011 from $1.4 million at December 31, 2010 primarily due to decreases in Lymphoseek development activities as well as normal fluctuations in timing of receipt and payment of invoices. Accrued liabilities and other increased to $2.1 million at December 31, 2011 from $1.0 million at December 31, 2010, primarily due to increased compensation, research and development, and professional services fees incurred during 2011 as well as costs related to the separation of Mr. Bupp. Accounts payable increased to $1.4 million at December 31, 2010 from $457,000 at December 31, 2009 primarily due to increases in Lymphoseek and RIGScan development activities as well as normal fluctuations in timing of receipt and payment of invoices. Accrued liabilities and other decreased slightly to $1.0 million at December 31, 2010 from $1.1 million at December 31, 2009, primarily due to decreased compensation, research and development, and professional services fees incurred during 2009. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our level of commercial and development activity related to Lymphoseek, and development activity related to AZD4694, RIGScan, and other potential product candidates.

Assets associated with discontinued operations decreased to $11,000 at December 31, 2011 from $3.0 million at December 31, 2010, and liabilities associated with discontinued operations decreased to $10,000 at December 31, 2011 from $1.8 million at December 31, 2010. Decreases in both assets and liabilities associated with discontinued operations were primarily due to the sale of the GDS Business and the disposition of the related extended warranty contracts during the second half of 2011. Assets associated with discontinued operations increased to $3.0 million at December 31, 2010 from $2.3 million at December 31, 2009, primarily due to increases in the assets of the GDS Business, mainly increases in accounts receivable and inventory offset by decreases in net property and equipment. Liabilities associated with discontinued operations increased to $1.8 million at December 31, 2010 from $1.7 million at December 31, 2009, primarily due to increases in deferred revenue related to the GDS Business.

Investing Activities. Investing activities provided $27.2 million of cash during 2011 compared to using $399,000 during 2010 and providing $327,000 during 2009. The sale of the GDS Business to Devicor in August 2011 and the disposition of the related extended warranty contracts in December 2011 provided a total of $27.4 million, net of related expenses. Available-for-sale securities of $494,000 matured during 2009. Capital expenditures of $184,000 during 2011 were primarily for software, computers, and office furniture. 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 expect our overall capital expenditures for 2012 will increase over 2011 as we purchase software required for Lymphoseek pharmacovigilance activities, open an office in the Boston area, and expand our Dublin office to accommodate anticipated headcount additions. Payments for patent and trademark costs were $53,000, $32,000 and $71,000 during 2011, 2010 and 2009, respectively.

Financing Activities. Financing activities provided $11.1 million of cash during 2011 compared to $6.3 million provided during 2010 and $3.2 million provided during 2009. The $11.1 million provided by financing activities during 2011 consisted primarily of $7.2 million of proceeds from the exercise of warrants and stock options, offset by $2.8 million paid for related tax withholdings primarily related to the separation of our former President and CEO, David Bupp, $7.0 million of cash received upon completion of a partially convertible debt agreement, offset by $189,000 paid for related debt issuance costs, payments of preferred stock dividends of $100,000, payments of notes payable of $62,000, and payments of capital leases of $9,000. The net $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 $478,000, payments of tax withholdings related to stock options exercised of $133,000, payments of preferred stock dividends of $111,000, payments of capital leases of $12,000, and payments of other 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 $219,000, payments of tax withholdings related to stock options exercised of $24,000, 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. Through November 2008, we sold to Fusion Capital under the agreement 7,568,671 shares of common stock for proceeds of $1.9 million and issued 954,000 shares as commitment fees. 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 unsold balance of the shares we originally had the right to sell to Fusion Capital under the original agreement, and as consideration for the amendment, we issued Fusion Capital an additional 360,000 shares, and agreed to issue an additional 486,000 shares of our common stock as a commitment fee pro rata as we sold 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.

As a condition of the SPA, Montaur required 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, we agreed to provide security for the obligations evidenced by the amended Bupp Note (the Amended Bupp Note), under the terms of a Security Agreement, dated December 26, 2007, by and between the Company and the Bupp Investors. 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 the achievement of a funding milestone set in the SPA, 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 the achievement of a further funding milestone set in the SPA, 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 of the Series A Preferred Stock was $1,000 and the conversion price was set at $0.50, thereby making the shares of Series A Preferred Stock convertible into an aggregate 6,000,000 shares of our common stock, subject to certain adjustments 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 requirement 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, the Company 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 public 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 the Company 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.

In January 2011, certain Series V 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 the Series V warrants, we reclassified $1.4 million in derivative liabilities related to those warrants to additional paid-in capital during the first quarter of 2011. Also in January 2011, certain 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 the Series CC and Series DD warrants, we reclassified $549,000 in derivative liabilities related to those warrants to additional paid-in capital during the first quarter of 2011.

During 2011, Mr. Bupp and certain members of his family exercised 810,000 Series V warrants in exchange for issuance of 810,000 shares of our common stock, resulting in gross proceeds of $255,600. The net effect of marking the derivative liabilities related to the exercised Series V warrants to market resulted in net increases in the estimated fair values of the derivative liabilities of $119,000, which were recorded as non-cash expense. As a result of the Series V warrant exercises, we reclassified $96,000 in derivative liabilities related to those warrants to additional paid-in capital.

Also during 2011, the holders of 60,000 Series Z warrants exercised them on a cashless basis in exchange for issuance of 46,902 shares of our common stock. The net effect of marking the derivative liabilities related to the exercised Series Z warrants to market resulted in net increases in the estimated fair values of the derivative liabilities of $79,000, which were recorded as non-cash expense. As a result of the Series Z warrant exercises, we reclassified $164,000 in derivative liabilities related to those warrants to additional paid-in capital.

In addition, the holders of Series CC warrants exercised them during 2011 in exchange for issuance of 1,578,948 shares of our common stock, resulting in gross proceeds of $3,331,580. Further, the holders of Series DD warrants exercised them during 2011 in exchange for issuance of 1,578,948 shares of our common stock, resulting in gross proceeds of $3,331,580. 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 $752,000, 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.

In May 2011, the Company's Board of Directors approved the sale of the GDS Business to Devicor. Our stockholders approved the Asset Sale at our Annual Meeting of Stockholders on August 15, 2011, and the Asset Sale closed on August 17, 2011. Under the terms of the APA, we sold the assets and assigned certain liabilities that were primarily related to the GDS Business. In exchange for the assets of the GDS Business, Devicor made cash payments to us of $30.3 million, assumed certain liabilities of the Company associated with the GDS Business as specified in the APA, and agreed to make royalty payments to us of up to an aggregate maximum amount of $20,000,000 based on the net revenue attributable to the GDS Business over the course of the next six fiscal years. In December 2011, we disposed of the extended warranty contracts related to the GDS Business, which were outstanding as of the date of the sale of the GDS Business but were not included in the August 2011 transaction. In exchange for transferring the liability related to the extended warranty contracts, which was previously recorded as deferred revenue, we made a cash payment to Devicor of $178,000. Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the GDS Business as a discontinued operation. Cash flows associated with the operation of the GDS Business have been combined within operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows. The Asset Sale will allow us to focus our resources and efforts on the continued development of our radiopharmaceutical products, and to pursue efforts to expand our drug development portfolio.

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules), providing for loans to the Company in two advances totaling $10 million. Pursuant to the Loan Agreement, we issued Hercules: (1) a Secured Term Promissory Note in the principal amount of $7,000,000 (the First Advance), bearing interest at the greater of either (a) the U.S. Prime Rate as reported in The Wall Street Journal plus 6.75%, or (b) 10.0% (effective interest rate at December 31, 2011 was 10.0%), and (2) a Series GG Warrant to purchase 333,333 shares of our common stock at an exercise price of $2.10 per share, expiring in December 2016 (the Series GG Warrant). Additionally, pursuant to the terms of the Loan Agreement, if FDA approval of Lymphoseek occurs on or before June 30, 2012, Navidea has the option to draw a second advance in the principal amount of $3,000,000 (the Second Advance), bearing interest at the same rate and payable on the same terms as the First Advance. The Loan Agreement provides for an interest-only period beginning on December 29, 2011 and expiring on July 1, 2012, provided the interest-only period shall expire on January 1, 2013 upon Navidea's receipt of FDA approval for Lymphoseek on or before June 30, 2012. The principal and interest is to be repaid in 30 equal monthly installments, payable on the first of each month following the expiration of the interest-only period. The outstanding balance of the debt is due December 1, 2014, or June 1, 2015 if the interest-only period is extended following FDA approval of Lymphoseek. Navidea has the option to pay up to $1.5 million of the principal amount of the debt in stock at a fixed conversion price of $2.77, subject to certain conditions. In addition, Hercules has the option to elect payment for up to another $1.5 million of the principal amount of the debt by conversion at a fixed conversion price of $2.77. The debt is collateralized by a security interest in substantially all of the Company's assets except for intellectual property, as to which the security interest is in rights to income or proceeds from the sale or licensing

thereof. The Loan Agreement also specifies certain covenants including the requirement that Navidea provide certain information, such as financial statements and budgets, on a periodic basis.

Our future liquidity and capital requirements will depend on a number of factors, including our ability to complete the development and commercialization of new products, our ability to achieve market acceptance of our 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, the ability to procure additional pipeline development opportunities, and intellectual property protection.

Our most significant near-term development priority is to continue our regulatory and pre-commercialization activities related to Lymphoseek. We expect Lymphoseek-related research and development expenditures to start to decline now that the NDA is under review by the FDA; however, we expect expenses related to Lymphoseek to increase in preparation for the commercial launch. We continue to assess timelines and development costs for development of AZD4694 and RIGScan. We are also actively evaluating a number of different product licensing and/or acquisition opportunities, including [^{123}I]-E-IACFT Injection, also called Altropane, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and movement disorders for which we executed a license option agreement in January 2012. Additional costs related to completing the license and subsequent development expenditures related to [^{123}I]-E-IACFT or some of the other late-stage radiopharmaceutical candidates we are evaluating, coupled with development costs related to our existing product candidates, may result in the use of a material portion of our available funds. We believe we have adequate financial resources, when considered with the flexibility of our development plans and anticipated cash flow following the commercialization of Lymphoseek, to permit us to fund some level of pipeline acquisition, licensing and development opportunities. However, we cannot assure you that Lymphoseek will achieve FDA approval, or if approved, that it will generate our expected levels of sales and cash flow. If Lymphoseek is not approved, or its approval is delayed, we may need to revise our operating and development plans.

We filed a shelf registration statement in 2011 to provide us with future funding alternatives and flexibility as we evaluate our strategic goals and plans for expansion of our product pipeline, although we have not decided whether, when or how much capital might be raised under the registration statement. Even if we decide to attempt to raise additional capital, we cannot assure you that we will be successful in doing so on terms acceptable to the Company, or at all. We also cannot assure you that we will be able to gain access and/or be able to execute on securing new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future. See Risk Factors.

Recent Accounting Developments

In May 2011, the Financial Accounting Standards Board (FASB) and International Accounting Standards Board (IASB) issued Accounting Standards Update (ASU) No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). ASU 2011-04 created a uniform framework for applying fair value measurement principles for companies around the world and clarified existing guidance in US GAAP. ASU 2011-04 is effective for interim and annual reporting periods beginning after December 15, 2011 and shall be applied prospectively. We do not expect ASU 2011-04 to have a material effect on our consolidated financial statements, however, it may result in additional disclosures.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (ASU 2011-05), as amended by ASU No. 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12). The ASUs increase the

prominence of items reported in other comprehensive income (OCI) by eliminating the option to present OCI as part of the statement of changes in stockholders' equity. The amendments require companies to present all non-owner changes in stockholders' equity, either as one continuous statement or as two separate but consecutive statements. The ASUs do not change the current option for presenting components of OCI gross of the effect of income taxes, provided that such tax effects are presented in the statement in which OCI is presented or disclosed in the notes to the financial statements. Additionally, the standard does not affect the calculation or reporting of earnings per share. The amendments are effective for interim and annual reporting periods beginning after December 15, 2011 and are to be applied retrospectively, with early adoption permitted. The Company adopted the provisions of ASU 2011-05 early which only impacted the presentation on the statement of operations and comprehensive income (loss). ASU 2011-12 also impacts presentation in the financial statements and will have no effect on our financial position or results of operations.

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 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 and restricted stock, are recognized in the statements of operations based on their estimated fair values on the date of grant. 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.

- *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 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 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 sheets at fair value in accordance with current accounting guidelines for such complex financial instruments. The fair value of warrant liabilities is determined based on a 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.

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Contractual Obligations and Commercial Commitments

The following table presents our contractual obligations and commercial commitments as of December 31, 2011.

	Payments Due By Period					
Contractual Cash Obligations	Total	2012	2013	2014	2015	2016 and After
Capital lease obligation	$12,650	$6,900	$5,750	$—	$ —	$ —
Operating leases	152,186	143,256	8,930	—	—	—
Unconditional purchase obligations (a)	651,700	651,700	—	—	—	—
Principal and interest on long-term debt	8,643,963	711,667	3,390,722	3,101,389	—	—
Total contractual cash obligations	$9,460,499	$1,513,522	$3,405,402	$3,101,389	$ —	$ —

(a) This amount represents purchases under binding purchase orders for which we are required to take delivery of the product under the terms of the underlying supply agreement going out approximately six months.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of December 31, 2011, our $28.6 million in cash was primarily invested in interest-bearing money market accounts. We believe that a hypothetical 10% increase or decrease in market interest rates would not have a material impact on our consolidated financial position, results of operations or cash flows.

Foreign Currency Exchange Rate Risk. We do not currently have material foreign currency exposure related to our assets as the majority are denominated in U.S. currency and our foreign-currency based transaction exchange risk is not material. For the years ended December 31, 2011, 2010 and 2009, we recorded approximately $3,000, $3,000 and $4,000 of foreign currency transaction losses, respectively.

Equity Price Risk. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. 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. The fair value of warrant liabilities is determined based on a Black-Scholes option pricing model calculation which includes the price of Company stock. As of December 31, 2011, we had approximately $569,000 of derivative liabilities recorded on our balance sheet related to 20,000 of our Series V warrants and 333,333 of our Series GG warrants. A hypothetical 50% increase in our stock price would increase the value of our derivative liabilities by approximately $400,000. A hypothetical 50% decrease in our stock price would decrease the value of our derivative liabilities by approximately

$360,000.

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 6, 2012 are set forth at pages F-1 through F-30 attached hereto.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

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

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, 2011. 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 system are met. Further, a design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments and decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons, or by management override of the control. Further, the design of any system of controls is also based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations of a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Management's Report on Internal Control Over Financial Reporting

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

Our 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, 2011. 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 concluded that, as of December 31, 2011, our internal control over financial reporting was effective based on those criteria. BDO USA, LLP, our independent registered public accounting firm, has issued an attestation report covering our internal control over financial reporting, which begins on page 55.

Changes in Internal Control Over Financial Reporting

During the year ended December 31, 2011, there were no changes in our internal control over financial reporting that materially affected, or are 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

Navidea Biopharmaceuticals, Inc.

Dublin, Ohio

We have audited Navidea Biopharmaceuticals, Inc.'s (formerly Neoprobe Corporation) internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Navidea Biopharmaceuticals, Inc.'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, Navidea Biopharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, 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 Navidea Biopharmaceuticals, Inc. as of December 31, 2011 and 2010, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011 and our report dated March 6, 2012 expressed an unqualified opinion on those consolidated financial statements.

/s/ BDO USA, LLP

Chicago, Illinois

March 6, 2012

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

Set forth below are the names and committee assignments of the persons who constitute our Board of Directors.

Name	Age	Committee(s)
Peter F. Drake, Ph.D.	58	Audit; Compensation, Nominating and Governance (Chairman)
Brendan A. Ford	53	Audit (Chairman); Compensation, Nominating and Governance
Jess Emery Jones, M.D.	33	Audit; Compensation, Nominating and Governance
Mark J. Pykett, V.M.D., Ph.D.	47	—
Eric K. Rowinsky, M.D.	55	—
Gordon A. Troup	58	Audit

Director Qualifications

The Board of Directors believes that individuals who serve on the Board should have demonstrated notable or significant achievements in their respective field; should possess the requisite intelligence, education and experience to make a significant contribution to the Board and bring a range of skills, diverse perspectives and backgrounds to its deliberations; and should have the highest ethical standards, a strong sense of professionalism and intense dedication to serving the interests of our stockholders. The following are qualifications, experience and skills for Board members which are important to our business and its future:

· *General Management.* Directors who have served in senior leadership positions are important to us as they bring experience and perspective in analyzing, shaping, and overseeing the execution of important operational and policy

issues at a senior level. These directors' insights and guidance, and their ability to assess and respond to situations encountered in serving on our Board of Directors, are enhanced by their leadership experience developed at businesses or organizations that operated on a global scale, faced significant competition, or involved other evolving business models.

- *Industry Knowledge.* Because we are a pharmaceutical development company, education or experience in our industry, including medicine, pharmaceutical development, distribution, or the regulatory environment, is important because such experience assists our Directors in understanding and advising our Company.
- *Business Development/Strategic Planning.* Directors who have a background in strategic planning, business development, mergers and acquisitions, and teamwork and process improvement provide insight into developing and implementing strategies for growing our business.
- *Finance/Accounting/Control.* Knowledge of capital markets, capital structure, financial control, audit, reporting, financial planning, and forecasting are important qualities of our directors because such qualities assist in understanding, advising, and overseeing our Company's capital structure, financing and investing activities, financial reporting, and internal control of such activities.
- *Board Experience/Governance.* Directors who have served on other public company boards can offer advice and insights with regard to the dynamics and operation of a board of directors, the relations of a board to the chief executive officer and other management personnel, the importance of particular agenda and oversight matters, and oversight of a changing mix of strategic, operational, and compliance-related matters.

Biographical Information

Set forth below is current biographical information about our directors, including the qualifications, experience and skills that make them suitable for service as a director. 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 2012 Annual Meeting:

Gordon A. Troup has served as a director of Navidea 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 a board member for several privately held companies.

Directors whose terms continue until the 2013 Annual Meeting:

Brendan A. Ford has served as a director of Navidea since July 2010. Since 2007, Mr. Ford has been a partner in Talisman Capital Partners, a private investment partnership focusing on middle-market companies. From 1991 through 2007, Mr. Ford served in various executive positions including Executive Vice President, Business Development and Corporate Strategy with Cardinal Health, Inc., primarily in capacities related to mergers, acquisitions and related strategic activities, and was involved in over $19 billion in acquisition and disposition transactions for Cardinal. Prior to his service with Cardinal Health, Mr. Ford practiced law with Baker and Hostetler from 1986 to 1991. From 1980 to 1983, Mr. Ford was employed by Touche Ross LLP as a certified public accountant. Mr. Ford has a B.S. in Business from Miami University, and a J.D. from The Ohio State University. Mr. Ford serves as a director and board committee member for several privately held companies.

Eric K. Rowinsky, M.D. has served as a director of Navidea since July 2010. In 2012, Dr. Rowinsky began serving as the Head of Research and Development, Chief Medical Officer, and Executive Vice President of Stemline Therapeutics, Inc., a discovery- and development-stage biotechnology company. In 2010, Dr. Rowinsky also co-founded Primrose Therapeutics, a start-up biotechnology company which was acquired in September 2011, and was a consultant in the area of new cancer drug development. From 2005 to December 2009, he served as the Chief Medical Officer and Executive Vice President of Clinical Development, Medical Affairs and Regulatory Affairs of

ImClone Systems Incorporated, a life sciences company, and was a principal consultant to the Lilly-ImClone Oncology Business Unit in 2010. Prior to that, Dr. Rowinsky held several positions at the Cancer Therapy & Research Center's Institute of Drug Development, including Director of the Institute, Director of Clinical Research and SBC Endowed Chair for Early Drug Development, and concurrently served as Clinical Professor of Medicine in the Division of Medical Oncology at the University of Texas Health Science Center at San Antonio. Dr. Rowinsky was an Associate Professor of Oncology at the Johns Hopkins University School of Medicine and on active staff at the Johns Hopkins School of Medicine from 1987 to 1996. Dr. Rowinsky is a member of the boards of directors of Biogen Idec, Inc. and of Coronado Biosciences, Inc., publicly-held life sciences companies. Dr. Rowinsky serves on the Compensation Committee at Biogen Idec. During the past five years, Dr. Rowinsky has also served as a director of Tapestry Pharmaceuticals, Inc. and ADVENTRX Pharmaceuticals, Inc., publicly-held life sciences companies. Dr. Rowinsky has extensive research and drug development experience, oncology expertise and broad scientific and medical knowledge.

Directors whose terms continue until the 2014 Annual Meeting:

Peter F. Drake, Ph.D. has served as a director of Navidea since April 2011. Dr. Drake began his career as a biotechnology analyst at Kidder, Peabody and Co. where he was a partner and head of the Healthcare Research Group. In 1988, Dr. Drake co-founded Vector Securities International, an investment banking firm specializing in the life sciences industry, where he was Executive Vice President and Director of Research. In 1993, Dr. Drake co-founded Vector Fund Management, a life sciences venture fund, and Deerfield Management, a healthcare hedge fund. In 1999, Vector Securities International was purchased by Prudential Securities, where he was a Managing Director and Head of Healthcare Research. Dr. Drake has served on the board of directors of Penwest Pharmaceuticals, a publicly traded specialty pharmaceutical company, which was purchased in 2010. He currently is a board member of Trustmark Insurance, a mutual insurance company; Rodman and Renshaw, a publicly traded investment banking firm; and Cortex Pharmaceuticals, a public neuroscience company. Dr. Drake received his undergraduate degree from Bowdoin College, and his Ph.D. in neurobiology and biochemistry from Bryn Mawr College.

Jess Emery Jones, M.D. has served as a director of Navidea since April 2011. He is currently the Chief Executive Officer of AngioLight, Inc. (formerly CorNova, Inc.). In addition to AngioLight, Dr. Jones is the Chief Executive Officer of NewCardio, Inc. Dr. Jones is also on the boards of directors of AngioLight, NewCardio, and NovaRay Inc. From October 2006 to January 2011, Dr. Jones worked with Vision Capital Advisors, LLC in New York City as the Director of Healthcare Investing, analyzing investment opportunities in the biotech, pharmaceutical, medical technology, and medical services fields, and assisted companies in the implementation of their business plans. From 2001 to 2007, Dr. Jones attended Columbia College of Physicians & Surgeons in New York City, where he received his medical degree in May 2007. In 2005, while attending Columbia Medical School in New York City, Dr. Jones was awarded an American Heart Association - Medical Student Research Fellowship to study post-stroke inflammatory mediators in the Department of Neurosurgery. Additionally, Dr. Jones earned a B.A. degree from the University of Utah in 2001 and an M.B.A. from Columbia Business School in May 2007.

Mark J. Pykett, V.M.D, Ph.D. has been President and Chief Executive Officer of Navidea since April 2011 and as a director of Navidea since August 2011. He has more than 15 years of pharmaceutical industry executive and operational management, strategic planning, and cross-functional drug development program oversight. He has led multiple companies focusing on research through commercialization in numerous indication areas and has particular expertise in guiding the development of biopharmaceutical product candidates. His leadership and industry knowledge have led to numerous international speaking and panel presentations at investment, industry, scientific and medical conferences. Prior to joining Navidea as Executive Vice President and Chief Development Officer in November 2010, Dr. Pykett served as Founding CEO of Talaris Advisors LLC, a strategic drug-development company serving the biotech industry. Dr. Pykett was President and Chief Operating Officer of Alseres Pharmaceuticals, a clinical stage biotech firm that focused on the development of radiopharmaceutical imaging agents for diagnosis of neurodegenerative disorders, as well as therapeutics for central nervous system indications. Dr. Pykett also held senior executive roles at several public and private biotechnology companies which have focused on therapeutics, diagnostics and medical devices. Dr. Pykett has also served as a Director of several public, private and not-for-profit organizations. Dr. Pykett graduated Phi Beta Kappa, Summa Cum Laude from Amherst College, holds a veterinary degree, Phi Zeta, Summa Cum Laude and a doctorate in molecular biology from the University of Pennsylvania, and received an M.B.A., Beta Gamma Sigma, from Northeastern University. He completed post-doctoral fellowships at

the University of Pennsylvania and Harvard University. Dr. Pykett held an adjunct faculty position at the Harvard School of Public Health from 1997 to 2004 and served on Northeastern University's Center for Enterprise Growth Corporate Advisory Board.

Executive Officers

In addition to Dr. Pykett, the following individuals are executive officers of Navidea and serve in the position(s) indicated below:

Name	Age	Position
Rodger A. Brown	61	Vice President, Regulatory Affairs and Quality Assurance
Frederick O. Cope, Ph.D.	65	Senior Vice President, Pharmaceutical Research and Clinical Development
Brent L. Larson	48	Senior Vice President; Chief Financial Officer; Treasurer and Secretary
Thomas H. Tulip, Ph.D.	59	Executive Vice President and Chief Business Officer

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

Frederick O. Cope, Ph.D., F.A.C.N., C.N.S., has served as Senior Vice President, Pharmaceutical Research and Clinical Development of Navidea since July 2010 and as Vice President, Pharmaceutical Research and Clinical Development from February 2009 to July 2010. Prior to accepting his position with Navidea, Dr. Cope served as the Assistant Director for Research and Head of Program Research Development for The Ohio State University Comprehensive Cancer Center, The James Cancer Hospital and The Richard J. Solove Research Institute, from April 2001 to February 2009. Dr. Cope also served as head of the Cancer and AIDS product development and commercialization program for the ROSS/Abbott Laboratories division for 10 years, and head of human and veterinary vaccine production and improvement group for Wyeth Laboratories for seven years. Dr. Cope served a fellowship in oncology at the McArdle Laboratory for Cancer Research at the University of Wisconsin and the honored scientist in residence at the National Cancer Center Research Institute in Tokyo; he is the recipient of the Ernst W. Volwiler Research Award. Dr. Cope is also active in a number of professional and scientific organizations such as serving as an editorial reviewer for several professional journals, and as an advisor/director to the research program of Roswell Park Memorial Cancer Center. Dr. Cope received his B.Sc. from the Delaware Valley College of Science and Agriculture, his M.S. from Millersville University of Pennsylvania and his Ph.D. from the University of Connecticut with full honors.

Brent L. Larson has served as Senior Vice President of Navidea since July 2010, as Chief Financial Officer and Treasurer since February 1999 and as Secretary since 2003. Prior to that, Mr. Larson served as our Vice President, Finance from July 1998 to July 2010 and as Controller from July 1996 to June 1998. Before joining Navidea, Mr. Larson was employed by Price Waterhouse LLP. Mr. Larson has a B.B.A. degree in accounting from Iowa State University of Science and Technology and is a Certified Public Accountant.

Thomas H. Tulip, Ph.D., has served as Executive Vice President and Chief Business Officer of Navidea since June 2011. Dr. Tulip has held senior leadership positions at Alseres Pharmaceuticals, Lantheus Medical Imaging, Bristol Myers Squibb (BMS) and DuPont, where his roles spanned product discovery and development, business and technology planning, brand and alliance management and international business management. Most recently, as President, Alseres Molecular Imaging, Dr. Tulip led efforts to develop markets for a Phase III neuroimaging agent. While at DuPont and BMS prior to Alseres, he was instrumental in the development, commercialization and international management of the highly successful nuclear cardiology franchise, successfully built the BMS Medical Imaging international business, and led planning activities for innovative PET tracers at Lantheus/BMS. Dr. Tulip earned a B.S. from University of Vermont, and an M.S. and Ph.D. from Northwestern University. He was a visiting scholar at Osaka University and served as adjunct professor at Northeastern University. Dr. Tulip serves on the board of directors of the Medical Imaging Technology Association (MITA) and leads its PET Working Group in the Molecular Imaging Section. He was recently Chairperson of the Institute for Molecular Technologies (IMT) and held numerous leadership positions there. He served on the Board of the Academy of Molecular Imaging, including as its Treasurer. Dr. Tulip was Chairperson for the Society of Nuclear Medicine (SNM) Corporate Advisory Board and has been active in a number of Council on Radionuclides and Radiopharmaceuticals (CORAR) committees, now serving on its Board of Directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and greater than 10% stockholders, to file reports of ownership and changes in ownership of our securities with the Securities and Exchange Commission. Copies of the reports are required by SEC regulation to be furnished to us. Based on our review of these reports and written representations from reporting persons, we believe that all reporting persons complied with all filing requirements during the fiscal year ended December 31, 2011, except for: (i) David C. Bupp, who had two late Form 4 filings, one related to restricted stock which vested in April 2011, and one related to Company stock that he sold on the open market in November 2011, (ii) Peter F. Drake, Ph.D., who had one late Form 4 filing related to Company stock that he purchased on the open market in September 2011, (iii) Eric K. Rowinsky, M.D., who had one late Form 4 filing related to restricted stock which vested in December 2011, and (iv) Thomas H. Tulip, Ph.D., who had one late Form 3 filing related to becoming an officer of the Company in June 2011 and one late Form 4 filing related to restricted stock which vested in December 2011.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to our directors, officers and all employees. The code of business conduct and ethics is posted on our website at www.neoprobe.com. The code of business conduct and ethics may be also obtained free of charge by writing to Navidea Biopharmaceuticals, Inc., Attn: Chief Financial Officer, 425 Metro Place North, Suite 450, Dublin, Ohio 43017.

Corporate Governance

Our Board of Directors is responsible for establishing broad corporate policies and reviewing our overall performance rather than day-to-day operations. The primary responsibility of our Board is to oversee the management of Navidea and, in doing so, serve the best interests of the Company and our stockholders. Our Board selects, evaluates and provides for the succession of executive officers and, subject to stockholder election, directors. It reviews and approves corporate objectives and strategies, and evaluates significant policies and proposed major commitments of corporate resources. Our Board also participates in decisions that have a potential major economic impact on the Company. Management keeps our directors informed of Company activity through regular communication, including written reports and presentations at Board and committee meetings.

Board of Directors Meetings

Our Board of Directors held a total of twenty-four meetings in the fiscal year ended December 31, 2011, and each of the directors attended at least 75 percent of the aggregate number of meetings of the Board of Directors and committees (if any) on which he served. It is our policy that all directors attend the Annual Meeting of Stockholders. However, conflicts and unforeseen events may prevent the attendance of a director, or directors. All members of our Board of Directors attended the 2011 Annual Meeting of Stockholders.

The Board of Directors maintains the following committees to assist it in its oversight responsibilities. The current membership of each committee is indicated in the list of directors set forth under “Board of Directors” above.

Audit Committee

The Audit Committee of the Board of Directors selects our independent registered public accounting firm with whom the Audit Committee reviews the scope of audit and non-audit assignments and related fees, the accounting principles that we use in financial reporting, and the adequacy of our internal control procedures. The members of our Audit Committee are: Brendan A. Ford (Chairman), Peter F. Drake, Ph.D., Jess Emery Jones, M.D., and Gordon A. Troup, each of whom is “independent” under Section 803A of the NYSE Amex Company Guide. The Board of Directors has determined that Brendan A. Ford meets the requirements of an “audit committee financial expert” as set forth in Section 407(d)(5) of Regulation S-K promulgated by the SEC. The Audit Committee held five meetings in the fiscal year ended December 31, 2011. The Board of Directors adopted a written Amended and Restated Audit Committee Charter on April 30, 2004. A copy of the Amended and Restated Audit Committee Charter is posted on the Company’s website at www.navidea.com.

Compensation, Nominating and Governance Committee

The Compensation, Nominating and Governance (CNG) Committee of the Board of Directors discharges the Board’s responsibilities relating to the compensation of the Company's directors, executive officers and associates, identifies and recommends to the Board of Directors nominees for election to the Board, and assists the Board in the implementation of sound corporate governance principles and practices. With respect to its compensation functions, the CNG Committee evaluates and approves executive officer compensation and reviews and makes recommendations to the Board with respect to director compensation, including incentive or equity-based compensation plans; reviews and evaluates any discussion and analysis of executive officer and director compensation included in the Company’s annual report or proxy statement, and prepares and approves any report on executive officer and director compensation for inclusion in the Company’s annual report or proxy statement required by applicable rules and regulations; and monitors and evaluates, at the Committee’s discretion, matters relating to the compensation and benefits structure of the Company and such other domestic and foreign subsidiaries or affiliates, as it deems appropriate. The members of our CNG Committee are: Peter F. Drake, Ph.D. (Chairman), Brendan A. Ford, and Jess Emery Jones, M.D. The CNG Committee held six meetings in the fiscal year ended December 31, 2011. The Board of Directors adopted a written Compensation, Nominating and Governance Committee Charter on February 26, 2009. A copy of the Compensation, Nominating and Governance Committee Charter is posted on the Company’s website at www.navidea.com.

Board of Directors Leadership Structure

Our Board of Directors has determined that it is in the best interests of the Company and its stockholders that the roles of Chairman of the Board and Chief Executive Officer be held by different individuals within our organization. Our Chief Executive Officer is responsible for setting the strategic direction for the Company and the day-to-day leadership and performance of the Company, while the Chairman of the Board provides strategic guidance and presides over meetings of the full Board of Directors. The Board of Directors believes that this structure helps facilitate the role of the independent directors in the oversight of the Company and the active participation of the independent directors in setting agendas and establishing priorities and procedures that work for the Board of Directors. The Chairman of the Board also acts as a key liaison between the Board of Directors and management. Moreover, in addition to feedback provided during the course of meetings of the Board of Directors, our independent directors have executive sessions led by the Chairman of the Board. Our Chairman of the Board acts as a liaison between the independent directors and the Chief Executive Officer regarding any specific feedback or issues following an executive session of independent directors, provides the Chief Executive Officer with input regarding agenda items for Board of Director and committee meetings, and coordinates with the Chief Executive Officer regarding information to be provided to the independent directors in performing their duties.

Board of Directors Role in Risk Oversight

Our Chief Executive Officer and senior management are responsible for the day-to-day management of the risks we face. Our Board of Directors, as a whole and through its committees, has responsibility for the oversight of risk management, including general oversight of (i) the financial exposure of the Company, (ii) risk exposure as related to overall company portfolio and impact on earnings, (iii), oversight for information technology security and risk, and (iv) all systems, processes, and organizational structures and people responsible for finance and risk functions. Certain risks are overseen by committees of the Board of Directors and these committees make reports to the full Board of Directors, including reports on noteworthy risk management issues. Financial risks are overseen by the Audit Committee which meets with management to review the Company's major financial risk exposure and the steps management has taken to monitor and control such exposures. Compensation risks are overseen by the CNG Committee.

Members of the Company's senior management report to the full Board of Directors about their areas of responsibility, including reports regarding risk within such area of responsibility and the steps management has taken to monitor and control such exposures. Additional review or reporting of risks is conducted as needed or as requested by the Board of Directors or committee.

Item 11. Executive Compensation

Compensation Discussion and Analysis

Overview of Compensation Program. The CNG Committee of the Board of Directors is responsible for establishing and implementing our compensation policies applicable to senior executives and monitoring our compensation practices. The CNG Committee seeks to ensure that our compensation plans are fair, reasonable and competitive. The CNG Committee is responsible for reviewing and approving all senior executive compensation, all awards under our cash bonus plan, and awards under our equity-based compensation plans.

Philosophy and Goals of Executive Compensation Plans. The CNG Committee's philosophy for executive compensation is to:

- Pay for performance — The CNG Committee believes that our executives should be compensated based upon their ability to achieve specific operational and strategic results. Therefore, our compensation plans are designed to provide rewards for the individual's contribution to our performance.

- Pay commensurate with other companies categorized as value creators — The CNG Committee has set a goal that the Company should move towards compensation levels for senior executives that are, at a minimum, at the 40th to 50th percentile for similar executives in the workforce. This allows us to attract, hire, reward and retain senior executives who continue to formulate and execute our strategic plans and drive exceptional results.

To ensure our programs are competitive, the CNG Committee reviews compensation information of peer companies, national data and trends in executive compensation to help determine the appropriateness of our plans and compensation levels. These reviews become the basis for the CNG Committee's decisions on compensation plans and individual executive compensation payments.

The CNG Committee has approved a variety of programs that work together to provide a combination of basic compensation and strong incentives. While it is important for us to provide certain base level salaries and benefits to remain competitive, the CNG Committee's objective is to provide compensation plans with incentive opportunities that motivate and reward executives for consistently achieving superior results. The CNG Committee designs our compensation plans to:

- Reward executives based upon overall company performance, their individual contributions and creation of stockholder value;
- Encourage top performers to make a long-term commitment to our Company; and
- Align executive incentive plans with the long-term interests of stockholders.

The CNG Committee reviews competitive information and individual compensation levels before each fiscal year. During the review process, the CNG Committee addresses the following questions:

- Do any existing compensation plans need to be adjusted to reflect changes in competitive practices, different market circumstances or changes to our strategic initiatives?
- Should any existing compensation plans be eliminated or new plans be added to the executive compensation programs?
- What are the compensation-related objectives for our compensation plans for the upcoming fiscal year?
- Based upon individual performance, what compensation modifications should be made to provide incentives for senior executives to perform at superior levels?

In addressing these questions, the CNG Committee considers input from management, outside compensation experts and published surveys of compensation levels and practices.

The CNG Committee does not believe that our compensation policies and practices for its employees give rise to risks that are reasonably likely to have a material adverse effect on the Company. As noted below, our incentive-based compensation is generally tied to Company financial performance (i.e., revenue or gross margin) or product development goals (i.e., clinical trial progress or regulatory milestones). The CNG Committee believes that the existence of these financial performance incentives creates a strong motivation for company employees to contribute towards the achievement of strong, sustainable financial and development performance, and believes that the Company has a strong set of internal controls that minimize the risk that financial performance can be misstated in order to achieve incentive compensation payouts.

In addition to the aforementioned considerations, the CNG Committee also takes into account the outcome of stockholder advisory votes, taken every three years, on the compensation of our Chief Executive Officer, Chief Financial Officer, and our other three highest-paid executive officers (the Named Executive Officers). Our stockholders approved the resolution relating to the compensation of our Named Executive Officers at the most recent

Annual Meeting of Stockholders held on August 15, 2011.

Scope of Authority of the CNG Committee. The Board of Directors has authorized the CNG Committee to establish the compensation programs for all executive officers and to provide oversight for compliance with our compensation philosophy. The CNG Committee delegates the day-to-day administration of the compensation plans to management (except with respect to our executive officers), but retains responsibility for ensuring that the plan administration is consistent with the Company's policies. Annually, the CNG Committee sets the compensation for our executive officers, including objectives and awards under incentive plans. The CNG Committee also makes recommendations to the Board of Directors on appropriate compensation for the non-employee directors. In addition to overseeing the compensation of executive officers, the CNG Committee approves all awards under short-term cash incentive and long-term equity-based compensation plans for all other employees. For more information on the CNG Committee's role, see the CNG Committee's charter, which can be found on our website at www.navidea.com.

Independent Compensation Expertise. The CNG Committee is authorized to retain independent experts to assist in evaluating executive compensation plans and in setting executive compensation levels. These experts provide information on trends and best practices so the CNG Committee can formulate ongoing plans for executive compensation. The CNG Committee retained Pearl Meyer & Partners as its independent expert to assist in the determination of the reasonableness and competitiveness of the executive compensation plans and senior executives' individual compensation levels for fiscal 2011.

For fiscal 2011, Pearl Meyer performed a benchmark compensation review of our key executive positions, including our Named Executive Officers. Pearl Meyer utilized both proprietary survey and proxy reported data from compensation peers, with market data aged to January 1, 2011 by an annualized rate of 3.4%, the expected pay increase in 2011 for executives in the life sciences industry.

In evaluating appropriate executive compensation, it is common practice to set targets at a point within the competitive marketplace. The CNG Committee sets its competitive compensation levels based upon its compensation philosophy. Following completion of the Pearl Meyer study for 2011, the CNG Committee noted that our overall executive compensation was, on average, below the 25th percentile for an established peer group of companies. Based upon the Pearl Meyer study, the CNG Committee has determined, over the course of the next few years, to move towards a total compensation target for senior executive positions at the 40th to 50th percentile of total compensation for the competitive market.

Peer Group Companies. In addition to the above survey analysis, the CNG Committee also reviewed the compensation levels at specific competitive benchmark companies. With input from management, the CNG Committee chose the peer companies because they are competitors within our industry, have similar business models to our Company or have comparable key executive positions. While the specific plans for these companies may or may not be used, it is helpful to review their compensation data to provide benchmarks for the overall compensation levels that will be used to attract, hire, retain and motivate our executives.

As competitors and similarly situated companies that compete for the same executive talent, the CNG Committee determined that the following peer group companies most closely matched the responsibilities and requirements of our executives:

Infinity Pharmaceuticals Inc.

Immunomedics Inc.

Oncogenex Pharmaceuticals

Arqule Inc.

Celldex Therapeutics Inc.

Curis Inc.

Exact Sciences Corp.

Cell Therapeutics Inc.

Cytogenix Inc.

Delcath Systems Inc.

Mela Sciences Inc.

Keryx Biopharmaceuticals Inc.

The CNG Committee used the publicly available compensation information for these companies to analyze our competitive position in the industry. The CNG Committee reviewed the base salaries, short-term and long term incentive plans and benefits of the executives of these companies to provide background and perspective in analyzing the compensation levels for our executives.

Specific Elements of Executive Compensation.

Base Salary. Using information gathered by Pearl Meyer, peer company data, national surveys, general compensation trend information and recommendations from management, the CNG Committee approved the fiscal 2011 base salaries for our senior executives. Base salaries for senior executives are set using the CNG Committee's philosophy that compensation should be competitive and based upon performance. Executives should expect that their base salaries, coupled with a cash bonus award, would provide them the opportunity to be compensated at or above the competitive market at the 40th to 50th percentile.

Based on competitive reviews of similar positions, industry salary trends, overall company results and individual performance, salary increases may be approved from time-to-time. The CNG Committee reviews and approves base salaries of all executive officers.

For fiscal 2011, using data from proprietary surveys as well as published proxy data, the CNG Committee noted that due to the discrepancy between the actual compensation and the target levels, that typical merit increase percentages for executive base salaries were not necessarily relevant. In setting specific base salary increases, the CNG Committee also considered competitive market data.

The following table shows the increases in base salaries for the Named Executive Officers that were approved for fiscal 2011 compared to the approved salaries for fiscal 2010:

Named Executive Officer	Fiscal 2011 Base Salary	Fiscal 2010 Base Salary	**Increase** [(a)]	
David C. Bupp [(b)]	$ 400,000	$ 355,000	12.7	%
Mark J. Pykett, V.M.D., Ph.D. [(c)]	375,000	325,000	15.4	%
Rodger A. Brown [(d)]	185,000	155,000	19.4	%
Frederick O. Cope, Ph.D. [(e)]	265,000	211,000	25.6	%
Brent L. Larson [(f)]	250,000	195,000	28.2	%
Thomas H. Tulip, Ph.D. [(g)]	300,000	—	N/A	

(a) 2011 salary increases reflect both merit increases and market adjustments that, based in part on the Pearl Meyer compensation study, the CNG Committee felt were necessary to remain competitive in the life sciences industry.

(b) Mr. Bupp retired from service as our President and Chief Executive Officer effective April 15, 2011. The amount shown for fiscal 2011 is the approved annual salary that Mr. Bupp was earning at the time of his retirement. The actual amount paid to Mr. Bupp during fiscal 2011 is shown under "Salary" in the Summary Compensation table below.

(c)

(d) Dr. Pykett was promoted to President and Chief Executive Officer effective April 15, 2011, and the increase in his salary reflects this promotion. The actual amount paid to Dr. Pykett during fiscal 2011 is shown under “Salary” in the Summary Compensation table below.

(e) Mr. Brown’s salary was increased to $165,000 effective January 1, 2011, and was increased to $185,000 effective August 23, 2011. The amount shown for fiscal 2011 is the annual salary in effect at the end of 2011. The actual amount paid to Mr. Brown during fiscal 2011 is shown under “Salary” in the Summary Compensation table below.

(f) Dr. Cope’s salary was increased to $245,000 effective January 1, 2011, and was increased to $265,000 effective August 23, 2011. The amount shown for fiscal 2011 is the annual salary in effect at the end of 2011. The actual amount paid to Dr. Cope during fiscal 2011 is shown under “Salary” in the Summary Compensation table below.

(g) Mr. Larson’s salary was increased to $207,000 effective January 1, 2011, and was increased to $250,000 effective August 23, 2011. The amount shown for fiscal 2011 is the annual salary in effect at the end of 2011. The actual amount paid to Mr. Larson during fiscal 2011 is shown under “Salary” in the Summary Compensation table below.

Dr. Tulip commenced employment with the Company effective June 1, 2011. The amount shown for fiscal 2011 is the approved annual salary of Dr. Tulip in effect at the end of 2011. The actual amount paid to Dr. Tulip during fiscal 2011 is shown under “Salary” in the Summary Compensation table below.

The CNG Committee has approved the following base salaries for fiscal 2012: Dr. Pykett, $425,000; Mr. Brown, $191,000; Dr. Cope, $271,000; Mr. Larson, $265,000; and Dr. Tulip, $300,000.

Short-Term Incentive Compensation. Our executive officers, along with all of our employees, are eligible to participate in our annual cash bonus program, which has four primary objectives:

- Attract, retain and motivate top-quality executives who can add significant value to the Company;
- Create an incentive compensation opportunity that is an integral part of the employee's total compensation program;
- Reward participants' contributions to the achievement of our business results; and
- Provide an incentive for individuals to achieve corporate objectives that are tied to our strategic goals.

The cash bonus compensation plan provides each participant with an opportunity to receive an annual cash bonus based on our Company's performance during the fiscal year. The following are the key provisions of the cash bonus compensation plan:

- The plan is administered by the CNG Committee, which has the power and authority to establish, adjust, pay or decline to pay the cash bonus for each participant, including the power and authority to increase or decrease the cash bonus otherwise payable to a participant. However, the Committee does not have the power to increase, or make adjustments that would have the effect of increasing, the cash bonus otherwise payable to any executive officer. The Committee has the right to delegate to the Chief Executive Officer its authority and responsibilities with respect to the cash bonuses payable to employees other than executive officers.
- All Company employees are eligible to participate.
- The CNG Committee is responsible for specifying the terms and conditions for earning cash bonuses, including establishing specific performance objectives. Cash bonuses payable to executive officers are intended to constitute "qualified performance-based compensation" for purposes of Section 162(m) of the Internal Revenue Code. Consequently, each cash bonus awarded to an executive officer must be conditioned on one or more specified "Performance Measures," calculated on a consolidated basis. Possible Performance Measures include revenues; gross margin; operating income; net income; clinical trial progress; regulatory milestones; or any other performance objective approved by the CNG Committee.
- As soon as reasonably practicable after the end of each fiscal year, the CNG Committee determines whether and to what extent each specified business performance objective has been achieved and the amount of the cash bonus to be paid to each participant.

At the beginning of fiscal 2011, the CNG Committee established the fiscal 2011 targets and performance measures for all Company employees. For fiscal 2011, the cash bonus for each executive officer was a function of the designated target bonus amount (stated as a percentage of base salary and pro-rated based on time served at each salary level during fiscal 2011) and certain business performance objectives, weighted as a percentage of the total target amount. The business performance objectives established for fiscal 2011 are as follows:

- Achievement of specified 2011 annual revenue and gross margin goals for the Company's medical device and radiopharmaceutical product lines, subject to 20% reduction of bonus if not achieved.
- Completion of Phase 3 clinical activities for Lymphoseek, a proprietary radioactive lymphatic mapping targeting agent being developed by the Company, and the successful filing of a new drug application (NDA) with the United

States Food and Drug Administration (FDA) for Lymphoseek, subject to 40% reduction of bonus if not achieved.

- The successful development and implementation of a clinical development plan and strategy for a product utilizing the Company's RIGS technology, with either FDA or the European Medicines Agency (EMA), the centralized regulatory agency for the European Union, subject to 30% reduction of bonus if not achieved.
- Discretionary bonus, equal to 10% of the total bonus objective.

For the Named Executive Officers, the CNG Committee established the following cash bonus targets for fiscal 2011:

Named Executive Officer	Target Cash Bonus (% of Salary)		Target Cash Bonus ($ Amount)
David C. Bupp [(a)]	N/A		$ 60,000
Mark J. Pykett, V.M.D., Ph.D. [(b)]	50.0	%	180,377
Rodger A. Brown	17.4	%	30,000
Frederick O. Cope, Ph.D.	25.8	%	65,000
Brent L. Larson	20.2	%	45,000
Thomas H. Tulip, Ph.D. [(c)]	35.0	%	61,562

(a) Mr. Bupp retired from service as our President and Chief Executive Officer effective April 15, 2011. Mr. Bupp's target cash bonus for fiscal 2011 represents a pro-rated amount based on time served in his position and was established in his separation agreement.

(b) Dr. Pykett was promoted from Executive Vice President and Chief Business Officer to President and Chief Executive Officer effective April 15, 2011. Dr. Pykett's target cash bonus for fiscal 2011 represents a pro-rated amount based on time served at each salary level in each position.

(c) Dr. Tulip commenced employment with the Company effective June 1, 2011. Dr. Tulip's target cash bonus for fiscal 2011 represents a pro-rated amount based on time served in his position during fiscal 2011.

During a meeting in February 2012, the CNG Committee determined that the Company's mission, strategy and objectives changed significantly since the time when the original corporate objectives and individual bonus targets were established, and a number of significant positive accomplishments were achieved by the Company during the year that were not contemplated in establishing 2011 goals. With respect to the first objective, the sale of the Company's GDS Business affected the Company's ability to meet the pre-specified goal relating to revenue. However, as a result of the pro-rata achievement of the revenue goal through the point of the sale, coupled with the benefits to the Company's financial position of the sale itself, the CNG Committee considered that goal fully achieved. With regard to the second objective, the Committee concluded that the filing and subsequent acceptance of the NDA evidenced the successful achievement of that goal. In reviewing the third and fourth objectives, the Committee concluded that while progress had been made on the RIGS technology through gaining regulatory feedback on RIGS from both FDA and EMA and the activities associated with the transition to a humanized RIGS antibody, that the number of unanticipated incremental accomplishments which management and the staff of the Company had achieved should be recognized in assessing bonuses related to 2011 performance. Representative of these incremental accomplishments were the listing on a major national stock exchange, the sale of the GDS Business, the in-licensing of the AZD4694 Alzheimer's PET agent from AstraZeneca, the closing of a $7.0 million debt transaction, and overall appreciation of the stock price for the year. The CNG Committee therefore determined, at its discretion, that the 30% portion of the bonus attributable to the RIGS objective should be combined with the original 10% discretionary objective to create an overall 40% discretionary portion of the overall bonus objectives. With respect to the 40% discretionary portion, the progress on RIGS, as well as the recognition of the incremental accomplishments described above, were evaluated in assessing the Company's overall successes for the year. After reviewing the business performance objectives and the related proposed payouts, the CNG Committee approved the total cash bonus payouts for each employee of the Company. The approved cash bonus payouts to the Named Executive Officers, expected to be paid in March 2012, are shown under "Non-Equity Incentive Plan Compensation" in the Summary Compensation table below.

The CNG Committee has approved the following target cash bonus amounts (stated as a percentage of base salary) for fiscal 2012: Dr. Pykett, 50.0%; Mr. Brown, 20.0%; Dr. Cope, 25.0%; Mr. Larson, 27.5%; and Dr. Tulip, 35%.

The business performance objectives for 2012 have not yet been established by the CNG Committee for fiscal 2012.

Long-Term Incentive Compensation. All Company employees are eligible to receive equity awards in the form of stock options or restricted stock. Equity instruments awarded under the Company's equity-based compensation plan are based on the following criteria:

- Analysis of competitive information for comparable positions;
- Evaluation of the value added to the Company by hiring or retaining specific employees; and
- Each employee's long-term potential contributions to our Company.

Although equity awards may be made at any time as determined by the CNG Committee, they are generally made to all employees once per year or on the recipient's hire date in the case of new-hire grants.

The CNG Committee's philosophy on equity awards is that equity-based compensation is an effective method to align the interests of stockholders and management and focus management's attention on long-term results. When awarding equity-based compensation the CNG Committee considers the impact the participant can have on our overall performance, strategic direction, financial results and stockholder value. Therefore, equity awards are primarily based upon the participant's position in the organization, competitive necessity and individual performance. Stock option awards have vesting schedules over several years to promote long-term performance and retention of the recipient, and restricted stock awards include specific performance criteria for vesting.

On April 15, 2011, the Company granted 50,000 shares of restricted stock to Mark J. Pykett in connection with his promotion to President and Chief Executive Officer. Dr. Pykett's restricted stock will vest upon the first regulatory approval of a Lymphoseek product by either FDA or EMA, or upon the occurrence of a change in control as defined in the restricted stock agreement. If the employment of Dr. Pykett with the Company is terminated for reasons other than a change in control before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreements all restricted shares that have not vested at the effective date of Dr. Pykett's termination shall immediately be forfeited by Dr. Pykett.

On June 1, 2011, in connection with hiring Thomas H. Tulip as the Company's Executive Vice President and Chief Business Officer, the Company granted 80,000 shares of restricted stock to Dr. Tulip with the following vesting terms:

- 20,000 of the restricted shares vested upon the completion of the AstraZeneca license agreement on December 9, 2011;
- 20,000 will vest upon the partnering of Lymphoseek in Europe covering at least four countries;
- 20,000 will vest upon the partnering of Lymphoseek in Asia covering either Japan or at least two other countries; and
- 20,000 will vest upon the achievement of annual revenue to the Company from Cardinal Health, Inc. related to Lymphoseek of over $2 million per month for three consecutive months following the receipt of commercial marketing clearance in the U.S. if achieved before the 24th month following such marketing clearance.

All of Dr. Tulip's restricted shares vest upon the occurrence of a change in control as defined in Dr. Tulip's employment agreement, or if Dr. Tulip is terminated without cause as defined in his employment agreement. If the employment of Dr. Tulip with the Company is terminated for reasons other than a change in control or termination without cause before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreement all restricted shares that have not vested at the effective date of Dr. Tulip's termination shall immediately be forfeited by Dr. Tulip.

Also on June 1, 2011, in connection with hiring Dr. Tulip, the Company granted options to purchase 110,000 shares of common stock of the Company. Dr. Tulip's stock options have an exercise price of $4.93, vest as to one-fourth on each of the first four anniversaries of the date of grant, and expire on the tenth anniversary of the date of grant. If the employment of Dr. Tulip with the Company is terminated due to a change in control or without cause before all of the stock options have vested, then pursuant to the terms of the stock option award agreement all stock options that have not vested at the effective date of Dr. Tulip's termination shall immediately vest and become exercisable.

Other Benefits and Perquisites. The Named Executive Officers participate in other benefit plans on the same terms as other employees. These plans include medical, dental, vision, disability and life insurance benefits, and our 401(k) retirement savings plan (the 401(k) Plan).

Our vacation policy allows employees to carry up to 40 hours of unused vacation time forward to the next fiscal year. Any unused vacation time in excess of the amount eligible for rollover is generally forfeited. However, from time to time, due to high demands on our employees during a given fiscal year, we may elect to pay out for unused vacation time in excess of the amount eligible for rollover. The amount paid is calculated based on the employee's salary in effect at the end of the fiscal year to which the unused vacation time relates.

Our Named Executive Officers are considered "key employees" for purposes of IRC Section 125 Plan non-discrimination testing. Based on such non-discrimination testing, we determined that our Section 125 Plan was "top-heavy". As such, our key employees are ineligible to participate in the Section 125 Plan and are unable to pay their portion of medical, dental, and vision premiums on a pre-tax basis. As a result, the Company reimburses its key employees an amount equal to the lost tax benefit.

We pay group life insurance premiums on behalf of all employees, including the Named Executive Officers. The benefit provides life insurance coverage at two times the employee's annual salary plus $10,000, up to a maximum of $630,000.

We also pay group long-term disability insurance premiums on behalf of all employees, including the Named Executive Officers. The benefit provides long-term disability insurance coverage at 60% of the employee's annual salary, up to a maximum of $10,000 per month, beginning 180 days after the date of disability and continuing through age 65.

401(k) Retirement Plan. All employees are given an opportunity to participate in our 401(k) retirement savings plan (the 401(k) Plan), following a new-hire waiting period. The 401(k) Plan allows participants to have pre-tax amounts withheld from their pay and provides for a discretionary employer matching contribution (currently, a 40% match in the form of our common stock up to 5% of salary). Participants may invest their contributions in various fund options, but are prohibited from investing their contributions in our common stock. Participants are immediately vested in both their contributions and company matching contributions. The 401(k) Plan qualifies under section 401 of the Internal Revenue Code, which provides that employee and company contributions and income earned on contributions are not taxable to the employee until withdrawn from the Plan, and that we may deduct our contributions when made.

Employment Agreements

Our executive officers are employed under employment agreements which specify the terms of their employment such as base salary, benefits, paid time off, and post-employment benefits as shown in the tables below. Our employment agreements also specify that if a change in control occurs with respect to our Company and the employment of an executive officer is concurrently or subsequently terminated:

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

then, the executive officer would be paid a severance payment as disclosed in the tables below. For purposes of such employment agreements, a change in control includes:

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

David C. Bupp. Prior to his separation on April 15, 2011, Mr. Bupp was employed under a 36-month employment agreement effective January 1, 2010. The employment agreement provided for an annual base salary of $355,000. Effective January 1, 2011, Mr. Bupp's annual base salary was increased to $400,000. Mr. Bupp's target cash bonus for fiscal 2011 is $60,000, which represents a pro-rated amount based on time served in his position and was established in his separation agreement.

Mark J. Pykett, V.M.D., Ph.D. Dr. Pykett is employed under an 18-month employment agreement effective April 15, 2011. The employment agreement provides for an annual base salary of $375,000. For the calendar year ending December 31, 2011, the CNG Committee has determined that the maximum bonus payment to Dr. Pykett will be $180,377, which was pro-rated to reflect the number of weeks during the 2011 calendar year in which the Company employed Dr. Pykett as President and Chief Executive Officer vs. the number of weeks Dr. Pykett served in his prior position as Executive Vice President and Chief Development Officer.

Rodger A. Brown. Mr. Brown is employed under a 24-month employment agreement effective January 1, 2011. The employment agreement provides for an annual base salary of $165,000. Effective August 23, 2011, Mr. Brown's annual base salary was increased to $185,000. For the calendar year ending December 31, 2011, the CNG Committee has determined that the maximum bonus payment to Mr. Brown will be $30,000.

Frederick O. Cope, Ph.D. Dr. Cope is employed under a 24-month employment agreement effective January 1, 2011. The employment agreement provides for an annual base salary of $245,000. Effective August 23, 2011, Dr. Cope's

annual base salary was increased to $265,000. For the calendar year ending December 31, 2011, the CNG Committee has determined that the maximum bonus payment to Dr. Cope will be $65,000.

Brent L. Larson. Mr. Larson is employed under a 24-month employment agreement effective January 1, 2011. The employment agreement provides for an annual base salary of $207,000. Effective August 23, 2011, Mr. Larson's annual base salary was increased to $250,000. For the calendar year ending December 31, 2011, the CNG Committee has determined that the maximum bonus payment to Mr. Larson will be $45,000.

Thomas H. Tulip, Ph.D. Dr. Tulip is employed under a 12-month employment agreement effective June 1, 2011. The employment agreement provides for an annual base salary of $300,000. For the calendar year ending December 31, 2011, the CNG Committee has determined that the maximum bonus payment to Dr. Tulip will be $82,500, pro-rated to reflect the number of weeks during the 2011 calendar year in which the Company employed Dr. Tulip as Executive Vice President and Chief Business Officer.

Post-Employment Compensation

The following tables set forth the expected benefit to be received by each of our Named Executive Officers, except for Mr. Bupp, who is no longer with the Company, in the event of his termination resulting from various scenarios, assuming a termination date of December 31, 2011 and a stock price of $2.62, our closing stock price on December 30, 2011.

David C. Bupp

Mr. Bupp was employed during fiscal 2011 under an employment agreement dated January 1, 2010. Pursuant to the employment agreement, Mr. Bupp served as our President and Chief Executive Officer until his separation from the Company effective April 15, 2011. Pursuant to a separation agreement effective April 15, 2011, the Company agreed to pay Mr. Bupp (i) a severance of $532,500, payable in 12 equal monthly installments beginning in May 2011, (ii) a bonus of $60,000, representing a pro-rated portion of his 2011 target bonus, payable in March 2012, (iii) accrued but unused vacation in the amount of $64,615, payable in May 2011, (iv) reimbursement of Mr. Bupp's reasonable legal fees and expenses incurred in the negotiation of his separation agreement, up to a maximum of $10,000, and (v) reimbursement of Mr. Bupp's business travel and entertainment expenses incurred through the termination date. We also agreed to allow Mr. Bupp and his spouse to continue to participate, at the Company's cost, in our group medical, dental and vision plans for a period of 36 months following the termination date.

The Company also agreed to allow one year for Mr. Bupp to exercise his 1,525,000 vested stock options for a period of one year from the termination date. However, Mr. Bupp exercised all 1,525,000 of his stock options on April 13, 2011. In addition, the Company agreed to treat Mr. Bupp's restricted stock awards as follows: (i) in accordance with the award agreements dated January 1, 2009 (400,000 shares), December 1, 2009 (300,000 shares), and December 20, 2010 (300,000 shares), Mr. Bupp's termination was treated as a "termination without cause" with the effect that such unvested restricted shares became fully vested as of the termination date; and (ii) with respect to the award agreement dated January 3, 2008 (300,000 shares), the award agreement was amended to have the effect that such unvested restricted shares will expire if they have not vested by December 31, 2012.

Mark J. Pykett, V.M.D., Ph.D.

	For Cause	Resignation	Death	Disability	End of Term	Without Cause	Change in Control
Cash payments:							
Severance (a)	$ —	$ —	$—	$—	$468,750	$468,750	$937,500
Disability supplement (b)	—	—	—	185,100	—	—	—
Paid time off (c)	14,423	14,423	14,423	14,423	14,423	14,423	14,423
2011 401(k) match (d)	3,139	3,139	3,139	3,139	3,139	3,139	3,139
Continuation of benefits (e)	—	—	18,208	18,208	—	18,208	18,208
Stock option vesting Acceleration (f)	—	—	—	—	122,666	122,666	122,666
Restricted stock vesting Acceleration (g)	—	—	—	—	—	130,950	916,650
Total	$ 17,562	$ 17,562	$35,770	$220,870	$608,978	$758,136	$2,012,586

(a) Severance amounts are pursuant to Dr. Pykett's employment agreement.

(b) During the first 6 months of disability, the Company will supplement disability insurance payments to Dr. Pykett to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays $100 per week for a maximum of 24 weeks.

(c) Amount represents the value of 80 hours of accrued but unused vacation time as of December 31, 2011.

(d) Amount represents the value of 1,198 shares of Company stock which was accrued during 2011 as the Company's 401(k) matching contribution but was unissued as of December 31, 2011, at $2.62, the closing price of the Company's stock on December 30, 2011.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2011.

(a) Pursuant to Dr. Pykett's stock option agreements, all unvested stock options outstanding will vest upon termination at the end of the term of his employment agreement, termination without cause, or a change in control. Amount represents the value of the stock at $2.62, the closing price of the Company's stock on December 30, 2011, less the exercise price of the options.

(f) Pursuant to Dr. Pykett's restricted stock agreements, certain unvested restricted stock outstanding will vest upon termination without cause or a change in control.

Rodger A. Brown

	For Cause	Resignation	Death	Disability	End of Term	Without Cause	Change in Control
Cash payments:							
Severance (a)	$ —	$ —	$—	$—	$165,000	$165,000	$247,500
Disability supplement (b)	—	—	—	90,100	—	—	—
Paid time off (c)	5,070	5,070	5,070	5,070	5,070	5,070	5,070
2011 401(k) match (d)	—	—	—	—	—	—	—

Continuation of benefits (e)	—	—	20,835	20,835	—	20,835	20,835
Stock option vesting Acceleration (f)	—	—	—	—	74,650	74,650	74,650
Restricted stock vesting Acceleration (g)	—	—	—	—	—	—	65,475
Total	$ 5,070	$ 5,070	$25,905	$116,005	$244,720	$265,555	$413,530

(a) Severance amounts are pursuant to Mr. Brown's employment agreement.

(b) During the first 6 months of disability, the Company will supplement disability insurance payments to Mr. Brown to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays $100 per week for a maximum of 24 weeks.

(c) Amount represents the value of 57 hours of accrued but unused vacation time as of December 31, 2011.

(d) Mr. Brown does not participate in the Company's 401(k) Plan.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2011.

(b) Pursuant to Mr. Brown's stock option agreements, all unvested stock options outstanding will vest upon termination at the end of the term of his employment agreement, termination without cause, or a change in control. Amount represents the value of the stock at $2.62, the closing price of the Company's stock on December 30, 2011, less the exercise price of the options.

(f) Pursuant to Mr. Brown's restricted stock agreements, certain unvested restricted stock outstanding will vest upon a change in control.

Frederick O. Cope, Ph.D.

	For Cause	Resignation	Death	Disability	End of Term	Without Cause	Change in Control
Cash payments:							
Severance (a)	$—	$—	$—	$—	$245,000	$245,000	$367,500
Disability supplement (b)	—	—	—	130,100	—	—	—
Paid time off (c)	10,192	10,192	10,192	10,192	10,192	10,192	10,192
2011 401(k) match (d)	4,462	4,462	4,462	4,462	4,462	4,462	4,462
Continuation of benefits (e)	—	—	26,338	26,338	—	26,338	26,338
Stock option vesting Acceleration (f)	—	—	—	—	102,800	102,800	102,800
Restricted stock vesting Acceleration (g)	—	—	—	—	—	—	458,325
Total	$ 14,654	$ 14,654	$40,992	$171,092	$362,454	$388,792	$969,617

(a) Severance amounts are pursuant to Dr. Cope's employment agreement.

(b) During the first 6 months of disability, the Company will supplement disability insurance payments to Dr. Cope to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays $100 per week for a maximum of 24 weeks.

(c) Amount represents the value of 80 hours of accrued but unused vacation time as of December 31, 2011.

(d) Amount represents the value of 1,703 shares of Company stock which was accrued during 2011 as the Company's 401(k) matching contribution but was unissued as of December 31, 2011, at $2.62, the closing price of the Company's stock on December 30, 2011.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2011.

(c) Pursuant to Dr. Cope's stock option agreements, all unvested stock options outstanding will vest upon termination at the end of the term of his employment agreement, termination without cause, or a change in control. Amount represents the value of the stock at $2.62, the closing price of the Company's stock on December 30, 2011, less the exercise price of the options.

(f) Pursuant to Dr. Cope's restricted stock agreements, certain unvested restricted stock outstanding will vest upon a change in control.

Brent L. Larson

	For Cause	Resignation	Death	Disability	End of Term	Without Cause	Change in Control
Cash payments:							
Severance (a)	$—	$—	$—	$—	$207,000	$207,000	$310,500
Disability supplement (b)	—	—	—	122,600	—	—	—
Paid time off (c)	9,615	9,615	9,615	9,615	9,615	9,615	9,615
2011 401(k) match (d)	4,601	4,601	4,601	4,601	4,601	4,601	4,601

Continuation of benefits (e)	—	—	20,970	20,970	—	20,970	20,970
Stock option vesting Acceleration (f)	—	—	—	—	106,216	106,216	106,216
Restricted stock vesting Acceleration (g)	—	—	—	—	—	—	196,425
Total	$ 14,216	$ 14,216	$35,186	$157,786	$327,432	$348,402	$648,327

(a) Severance amounts are pursuant to Mr. Larson's employment agreement.

(b) During the first 6 months of disability, the Company will supplement disability insurance payments to Mr. Larson to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays $100 per week for a maximum of 24 weeks.

(c) Amount represents the value of 80 hours of accrued but unused vacation time as of December 31, 2011.

(d) Amount represents the value of 1,756 shares of Company stock which was accrued during 2011 as the Company's 401(k) matching contribution but was unissued as of December 31, 2011, at $2.62, the closing price of the Company's stock December 30, 2011.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2011.

(d) Pursuant to Mr. Larson's stock option agreements, all unvested stock options outstanding will vest upon termination at the end of the term of his employment agreement, termination without cause, or a change in control. Amount represents the value of the stock at $2.62, the closing price of the Company's stock on December 30, 2011, less the exercise price of the options.

(f) Pursuant to Mr. Larson's restricted stock agreements, certain unvested restricted stock outstanding will vest upon a change in control.

Thomas H. Tulip, Ph.D.

	For Cause	Resignation	Death	Disability	End of Term	Without Cause	Change in Control
Cash payments:							
Severance (a)	$—	$—	$—	$—	$225,000	$225,000	$450,000
Disability supplement (b)	—	—	—	147,600	—	—	—
Paid time off (c)	10,385	10,385	10,385	10,385	10,385	10,385	10,385
2011 401(k) match (d)	2,463	2,463	2,463	2,463	2,463	2,463	2,463
Continuation of benefits (e)	—	—	—	—	—	—	—
Stock option vesting Acceleration (f)	—	—	—	—	—	—	—
Restricted stock vesting Acceleration (g)	—	—	—	—	—	—	—
Total	$ 12,847	$ 12,847	$12,847	$160,447	$237,847	$237,847	$462,847

(e) Severance amounts are pursuant to Dr. Tulip's employment agreement.

(f) During the first 6 months of disability, the Company will supplement disability insurance payments to Dr. Tulip to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays $100 per week for a maximum of 24 weeks.

(g) Amount represents the value of 72 hours of accrued but unused vacation time as of December 31, 2011.

(h) Amount represents the value of 940 shares of Company stock which was accrued during 2011 as the Company's 401(k) matching contribution but was unissued as of December 31, 2011, at $2.62, the closing price of the Company's stock on December 30, 2011.

(i) Dr. Tulip does not participate in the Company's medical, dental or vision insurance plans.

(j) Pursuant to Dr. Tulip's stock option agreements, all unvested stock options outstanding will vest upon termination at the end of the term of his employment agreement, termination without cause, or a change in control. Amount represents the value of the stock at $2.62, the closing price of the Company's stock on December 30, 2011, less the exercise price of the options.

(k) Dr. Tulip's restricted stock agreements do not include provisions for accelerated vesting.

Report of Compensation, Nominating and Governance Committee

The CNG Committee is responsible for establishing, reviewing and approving the Company's compensation philosophy and policies, reviewing and making recommendations to the Board regarding forms of compensation provided to the Company's directors and officers, reviewing and determining cash and equity awards for the Company's officers and other employees, and administering the Company's equity incentive plans.

In this context, the CNG Committee has reviewed and discussed with management the Compensation Discussion and Analysis included in this annual report on Form 10-K. In reliance on the review and discussions referred to above, the

CNG Committee recommended to the Board, and the Board has approved, that the Compensation Discussion and Analysis be included in this annual report on Form 10-K for filing with the SEC.

The Compensation, Nominating
and Governance Committee

Peter F. Drake, Ph.D. (Chairman)
Brendan A. Ford
Jess Emery Jones, M.D.

Compensation, Nominating and Governance Committee Interlocks and Insider Participation

The current members of our CNG Committee are: Peter F. Drake, Ph.D. (Chairman), Brendan A. Ford, and Jess Emery Jones, M.D. In addition, Mr. Aschinger and Dr. Rowinsky served on the CNG Committee during 2011. None of these individuals were at any time during the fiscal year ended December 31, 2011, or at any other time, an officer or employee of the Company.

Directors and Officers Who Were Directors or Served on the Compensation Committee of Another Company During Fiscal 2011

Mr. Ford was a member of the board of directors of Scottissue and TTT Holdings, and was a member of the compensation committee of NanoStatics Corporation, all privately held companies, during fiscal 2011. Dr. Jones was a member of the board of directors of AngioLight, Inc. (formerly CorNova, Inc.), NewCardio, Inc. and Novaray, Inc., all publicly traded companies, and was a member of the compensation committees of AngioLight, Inc. and NewCardio, Inc. during fiscal 2011. Dr. Pykett was a member of the compensation committee of ADVENTRX Pharmaceuticals, Inc., a publicly traded company, through June 2011. Dr. Rowinsky served on the boards of directors of Biogen Idec, Inc. and Coronado Biosciences, Inc., both publicly traded life sciences companies, and was a member of the compensation committee of Biogen Idec, Inc. during fiscal 2011. Dr. Tulip served on the boards of directors of the Medical Imaging Technology Association and the Council on Radionuclides and Radiopharmaceuticals, both private trade associations, during fiscal 2011.

Members of Our CNG Committee Who Were Executives of Another Company During Fiscal 2011

Dr. Drake was a member of our CNG Committee and served as a director on the boards of Trustmark Insurance, a mutual insurance company, Rodman and Renshaw, a publicly traded investment banking firm, and Cortex Pharmaceuticals, a publicly traded neuroscience company, during fiscal 2011. Mr. Ford was a member of our CNG Committee and served as a partner in Talisman Capital Partners, a private investment partnership, during fiscal 2011. Dr. Jones was a member of our CNG Committee and served as Chief Executive Officer of both AngioLight, Inc. and NewCardio, Inc., and as a director on the boards of AngioLight, Inc., NewCardio, Inc. and NovaRay, Inc., all publicly traded companies, during fiscal 2011. Dr. Rowinsky was a member of our CNG Committee and served as a director on the boards of Biogen Idec, Inc. and Coronado Biosciences, Inc., both publicly traded life sciences companies, and was a member of the compensation committee of Biogen Idec, Inc. during fiscal 2011.

Summary Compensation Table

The following table sets forth certain information concerning the annual and long-term compensation of our Named Executive Officers for the last three fiscal years.

Summary Compensation Table for Fiscal 2011

Named Executive Officer	Year	Salary	(a) Stock Awards	(b) Option Awards	(c) Non-Equity Incentive Plan Compensation	(d) All Other Compensation	Total Compensation
David C. Bupp (e)	2011	$536,282	$—	$—	$ 60,000	$ 9,967	$ 606,249
President and	2010	355,000	584,700	—	107,500	8,887	1,056,087
Chief Executive Officer	2009	335,000	565,308	—	45,000	8,621	953,929
Mark J. Pykett, V.M.D., Ph.D. (f)	2011	$363,249	$201,450	$—	$ 175,867	$ 7,431	$ 747,997
President and	2010	41,875	530,700	193,783	6,278	—	772,636
Chief Executive Officer	2009	—	—	—	—	—	—
Rodger A. Brown	2011	$172,347	$—	$—	$ 29,250	$ 7,096	$ 208,693
Vice President, Regulatory	2010	155,000	—	72,585	28,650	910	257,145
Affairs/Quality Assurance	2009	146,000	27,475	47,159	13,900	1,079	235,613
Frederick O. Cope, Ph.D. (g)	2011	$252,342	$—	$—	$ 63,375	$ 12,441	$ 328,158
Senior Vice President,	2010	211,000	—	145,169	51,375	5,980	413,524
Pharmaceutical Research and Clinical Development	2009	175,000	147,328	78,520	25,000	4,360	430,208
Brent L. Larson	2011	$222,637	$—	$—	$ 43,875	$ 10,438	$ 276,950
Senior Vice President and	2010	195,000	—	114,926	37,500	5,733	353,159
Chief Financial Officer	2009	184,000	82,426	65,247	15,313	4,934	351,920
Thomas H. Tulip, Ph.D. (h)	2011	$175,000	$394,320	$346,842	$ 60,023	$ 6,678	$ 982,863
Executive Vice President and	2010	—	—	—	—	—	—
Chief Business Officer	2009	—	—	—	—	—	—

(a) Amount represents the aggregate grant date fair value in accordance with FASB ASC Topic 718. Assumptions made in the valuation of stock awards are disclosed in Note 1(e) of the Notes to the Consolidated Financial

Statements in this Form 10-K.

(b) Amount represents the aggregate grant date fair value in accordance with FASB ASC Topic 718. Assumptions made in the valuation of option awards are disclosed in Note 1(e) of the Notes to the Consolidated Financial Statements in this Form 10-K.

(c) Amount represents the cash bonuses which have been approved by the CNG Committee and are disclosed for fiscal 2011, the year in which they were earned (i.e., the year to which the service relates).

(d) Amount represents additional compensation as disclosed in the All Other Compensation table below.

(e) Mr. Bupp retired from service as our President and Chief Executive Officer effective April 15, 2011.

(f) Dr. Pykett commenced employment with the Company effective November 15, 2010, and was promoted to President and Chief Executive Officer effective April 15, 2011.

(g) Dr. Cope commenced employment with the Company effective February 16, 2009.

(h) Dr. Tulip commenced employment with the Company effective June 1, 2011.

All Other Compensation

The following table describes each component of the amounts shown in the "All Other Compensation" column in the Summary Compensation table above.

All Other Compensation Table for Fiscal 2011

Named Executive Officer	Year	(a) Payment for Unused Vacation	(b) Value of Health Insurance Premiums	(c) Value of Life Insurance Premiums	(d) Value of Disability Insurance Premiums	(e) 401(k) Plan Employer Matching Contribution	(f) Other Benefits	Total All Other Compensation
David C. Bupp (f)	2011	$ 3,584	$ 227	$ 1,002	$ 213	$ 4,169	$ 772	$ 9,967
	2010	—	—	1,792	594	4,900	2,195	8,887
	2009	—	—	1,792	594	4,900	1,929	8,621
Mark J. Pykett, V.M.D., Ph.D. (g)	2011	$ —	$ 1,019	$ 2,003	$ 640	$ 3,769	$ —	$ 7,431
	2010	—	—	—	—	—	—	—
	2009	—	—	—	—	—	—	—
Rodger A. Brown	2011	$ 4,769	$ 694	$ 1,081	$ 552	$ —	$ —	$ 7,096
	2010	—	—	910	460	—	—	910
	2009	—	—	857	434	—	—	1,079
Frederick O. Cope, Ph.D. (h)	2011	$ 4,818	$ 678	$ 1,405	$ 640	$ 4,900	$ —	$ 12,441
	2010	—	—	1,229	594	4,751	—	5,980
	2009	—	—	851	446	3,509	—	4,360
Brent L. Larson	2011	$ 2,531	$ 1,019	$ 1,348	$ 640	$ 4,900	$ —	$ 10,438
	2010	—	—	1,138	579	4,595	—	5,733
	2009	—	—	1,079	546	4,008	—	4,934
Thomas H. Tulip, Ph.D. (i)	2011	$ —	$ 2,807	$ 650	$ 320	$ 2,901	$ —	$ 6,678
	2010	—	—	—	—	—	—	—
	2009	—	—	—	—	—	—	—

(a) Amount represents payment for unused vacation time in excess of the amount eligible for rollover in fiscal 2011. The amount paid is calculated based on the employee's salary in effect at the end of the fiscal year to which the

unused vacation time relates.

(b) Amount represents reimbursement of the lost tax benefit due to the ineligibility of our Named Executive Officers to pay their portion of medical, dental, and vision premiums on a pre-tax basis under our IRC Section 125 Plan.

(c) Amount represents group life insurance premiums paid on behalf of the Named Executive Officers.

(d) Amount represents group long-term disability insurance premiums paid on behalf of the Named Executive Officers.

(e) Amount represents the value of the common stock contributed to the Named Executive Officer's account in our 401(k) Plan as calculated on a quarterly basis.

(f) During his tenure as Chief Executive Officer, the Company reimbursed Mr. Bupp for membership dues at a private club where Mr. Bupp often conducted business meetings.

(g) Mr. Bupp retired from service as our President and Chief Executive Officer effective April 15, 2011.

(h) Dr. Pykett commenced employment with the Company effective November 15, 2010, and was promoted to President and Chief Executive Officer effective April 15, 2011.

(i) Dr. Cope commenced employment with the Company effective February 16, 2009.

(j) Dr. Tulip commenced employment with the Company effective June 1, 2011.

Grants of Plan-Based Awards

The following table sets forth certain information about plan-based awards that we made to the Named Executive Officers during fiscal 2011. For information about the plans under which these awards were granted, see the discussion under “Short-Term Incentive Compensation” and “Long-Term Incentive Compensation” in the “Compensation Discussion and Analysis” section above.

Grants of Plan-Based Awards Table for Fiscal 2011

Named Executive Officer	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards (a) Threshold	Maximum	Estimated Future Payouts Under Equity Incentive Plan Awards (b) Threshold	Maximum	All Other Stock Awards: Number of Shares of Stock	All Other Option Awards: Number of Securities Underlying Options	Exercise Price of Option Awards	Grant Date Fair Value of Stock and Option Awards	
David C. Bupp	N/A	$ —	$ 60,000	—	—	—	—	$ —	$ —	(a)
Mark J. Pykett, V.M.D., Ph.D.	N/A	$ —	$ 180,377	—	—	—	—	—	$ —	(a)
	4/15/2011	$ —	$ —	—	50,000	—	—	$ —	$ 201,450	(c)
Rodger A. Brown	N/A	$ —	$ 30,000	—	—	—	—	$ —	$ —	(a)
Frederick O. Cope ,Ph.D.	N/A	$ —	$ 65,000	—	—	—	—	$ —	$ —	(a)
Brent L. Larson	N/A	$ —	$ 45,000	—	—	—	—	$ —	$ —	(a)
Thomas H. Tulip, Ph.D.	N/A	$ —	$ 61,562	—	—	—	—	—	$ —	(a)
	6/1/2011	$ —	$ —	—	80,000	—	—	—	$ 394,320	(d)
	6/1/2011	$ —	$ —	—	—	—	110,000	$ 4.93	$ 346,842	(e)

(a) The threshold amount reflects the fact that no cash bonus awards would have been payable if none of the specified business performance objectives were achieved. The maximum amount reflects the target cash bonus awards

payable if all of the specified business performance objectives are achieved. For actual cash bonus award amounts, see the "Non-Equity Incentive Plan Compensation" column in the Summary Compensation table above.

(b) The threshold amount reflects the fact that no restricted stock awards will be payable if none of the vesting terms are achieved. The maximum amount reflects the target restricted stock awards payable if all of the vesting terms are achieved.

(c) These shares of restricted stock will vest upon the first regulatory approval of a Lymphoseek product by either FDA or EMA, or upon the occurrence of a change in control as defined in the restricted stock agreement. If the employment of Dr. Pykett with the Company is terminated for reasons other than a change in control before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreements all restricted shares that have not vested at the effective date of Dr. Pykett's termination shall immediately be forfeited by Dr. Pykett.

(d) These shares of restricted stock will vest according to the following terms:

- 20,000 of the restricted shares vested upon the completion of the AstraZeneca license agreement on December 9, 2011;
- 20,000 will vest upon the partnering of Lymphoseek in Europe covering at least four countries;
- 20,000 will vest upon the partnering of Lymphoseek in Asia covering either Japan or at least two other countries; and
- 20,000 will vest upon the achievement of annual revenue to the Company from Cardinal Health, Inc. related to Lymphoseek of over $2 million per month for three consecutive months following the receipt of commercial marketing clearance in the U.S., if achieved before the 24th month following such marketing clearance.

All of Dr. Tulip's restricted shares vest upon the occurrence of a change in control as defined in Dr. Tulip's employment agreement, or if Dr. Tulip is terminated without cause as defined in his employment agreement. If the employment of Dr. Tulip with the Company is terminated for reasons other than a change in control or termination without cause before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreement all restricted shares that have not vested at the effective date of Dr. Tulip's termination shall immediately be forfeited by Dr. Tulip.

(e) These stock options vest as to one-fourth on each of the first four anniversaries of the date of grant, and expire on the tenth anniversary of the date of grant. If the employment of Dr. Tulip with the Company is terminated due to a change in control or without cause before all of the stock options have vested, then pursuant to the terms of the Stock Option Award Agreement all stock options that have not vested at the effective date of Dr. Tulip's termination shall immediately vest and become exercisable.

Outstanding Equity Awards

The following table presents certain information concerning outstanding equity awards held by the Named Executive Officers as of December 31, 2011.

Outstanding Equity Awards Table at Fiscal 2011 Year-End

	Option Awards					Stock Awards Equity Incentive Plan Awards		
Named Executive Officer	Number of Securities Underlying Unexercised Options (#) Exercisable	Unexercisable	Option Exercise Price	Option Expiration Date	Note	Number of Unearned Shares	Market Value of Unearned **Shares (s)**	Note
David C. Bupp						300,000	$ 786,000	(m)
Mark J. Pykett, V.M.D., Ph.D.	66,667	133,333	$ 1.70	11/12/2010	(j)	300,000	$ 786,000	(p)
						50,000	$ 131,000	(q)
Rodger A. Brown	50,000	—	$ 0.49	7/28/2014	(b)	20,000	$ 52,400	(m)
	40,000	—	$ 0.39	12/10/2014	(c)	25,000	$ 65,500	(o)
	20,000	—	$ 0.26	12/27/2015	(d)			
	20,000	—	$ 0.27	12/15/2016	(e)			
	20,000	—	$ 0.362	1/3/2018	(f)			
	16,667	8,333	$ 0.59	1/5/2019	(g)			
	33,333	16,667	$ 1.10	10/30/2019	(i)			
	15,000	45,000	$ 1.90	12/21/2020	(k)			
Frederick O. Cope, Ph.D.	33,333	16,667	$ 0.65	2/16/2019	(h)	100,000	$ 262,000	(n)
	50,000	25,000	$ 1.10	10/30/2019	(i)	75,000	$ 196,500	(o)
	30,000	90,000	$ 1.90	12/21/2020	(k)			
Brent L. Larson	70,000	—	$ 0.30	1/7/2014	(a)	50,000	$ 131,000	(m)
	50,000	—	$ 0.49	7/28/2014	(b)	75,000	$ 196,500	(o)
	50,000	—	$ 0.39	12/10/2014	(c)			
	40,000	—	$ 0.26	12/27/2015	(c)			
	50,000	—	$ 0.27	12/15/2016	(e)			
	50,000	—	$ 0.362	1/3/2018	(f)			
	16,667	8,333	$ 0.59	1/5/2019	(g)			
	50,000	25,000	$ 1.10	10/30/2019	(i)			
	23,750	71,250	$ 1.90	12/21/2020	(k)			

Thomas H. Tulip, Ph.D.	—	110,000	$ 4.93	6/1/2011	(l)	60,000	$ 157,200	(r)

(a) Options were granted 1/7/2004 and vested as to one-third on each of the first three anniversaries of the date of grant.

(b) Options were granted 7/28/2004 and vested as to one-third on each of the first three anniversaries of the date of grant.

(c) Options were granted 12/10/2004 and vested as to one-third on each of the first three anniversaries of the date of grant.

(d) Options were granted 12/27/2005 and vested as to one-third immediately and on each of the first two anniversaries of the date of grant.

(e) Options were granted 12/15/2006 and vested as to one-third on each of the first three anniversaries of the date of grant.

(f) Options were granted 1/3/2008 and vested as to one-third on each of the first three anniversaries of the date of grant.

(g) Options were granted 1/5/2009 and vest as to one-third on each of the first three anniversaries of the date of grant.

(h) Options were granted 2/16/2009 and vest as to one-third on each of the first three anniversaries of the date of grant.

(i) Options were granted 10/30/2009 and vest as to one-third on each of the first three anniversaries of the date of grant.

(j) Options were granted 11/12/2010 and vest as to one-third on each of the first three anniversaries of the date of grant.

(k) Options were granted 12/21/2010 and vest as to one-fourth on each of the first four anniversaries of the date of grant.

(l) Options were granted 6/1/2011 and vest as to one-fourth on each of the first four anniversaries of the date of grant.

(m) Restricted shares granted January 3, 2008. Pursuant to the terms of restricted stock agreements between the Company and each grantee, the restricted shares will vest upon the approval of a NDA for Lymphoseek by FDA. If the employment of a grantee with the Company is terminated before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreements all restricted shares that have not vested at the effective date of such grantee’s termination shall immediately be forfeited by the grantee. Pursuant to its authority under Section 3.2 of the restricted stock agreements the CNG Committee eliminated the forfeiture provision in Section 3.2(b) of the restricted stock agreements effective January 1, 2009, which provision effected the forfeiture of the shares if the vesting event did not occur before June 30, 2010.

(n) Restricted shares granted February 16, 2009. Pursuant to the terms of the restricted stock agreement between the Company and Dr. Cope, 50% of the restricted shares will vest upon the approval of a NDA for Lymphoseek by FDA or the approval of marketing authorization for Lymphoseek by EMA and 50% of the restricted shares will vest upon the commencement of patient enrollment in a Phase 3 clinical trial in humans of RIGScan. All of the restricted shares vest upon the occurrence of a change in control as defined in Dr. Cope's employment agreement. If the employment of Dr. Cope with the Company is terminated for reasons other than a change in control before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreement all restricted shares that have not vested at the effective date of Dr. Cope's termination shall immediately be forfeited by Dr. Cope.

(o) Restricted shares granted December 1, 2009. Pursuant to the terms of restricted stock agreements between the Company and each grantee, the restricted shares will vest upon the approval of a NDA for Lymphoseek by FDA or the approval of marketing authorization for Lymphoseek by EMA. All of the restricted shares vest upon the occurrence of a change in control as defined in the restricted stock agreement. If the employment of a grantee with the Company is terminated for reasons other than a change in control before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreements all restricted shares that have not vested at the effective date of such grantee's termination shall immediately be forfeited by the grantee.

(p) Restricted shares granted November 15, 2010. Pursuant to the terms of the restricted stock agreement between the Company and Dr. Pykett, 125,000 of the restricted shares will vest upon the approval of a NDA for Lymphoseek by FDA or the approval of marketing authorization for Lymphoseek by EMA and 175,000 of the restricted shares will vest upon the approval of a NDA for a RIGS technology product by FDA or the approval of marketing authorization for a RIGS technology product by EMA. All of the restricted shares vest upon the occurrence of a change in control as defined in Dr. Pykett's employment agreement, or if Dr. Pykett is terminated without cause as defined in his employment agreement. If the employment of Dr. Pykett with the Company is terminated for reasons other than a change in control or without cause before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreement all restricted shares that have not vested at the effective date of Dr. Pykett's termination shall immediately be forfeited by Dr. Pykett.

(q) Restricted shares granted April 15, 2011. Pursuant to the terms of the restricted stock agreement between the Company and Dr. Pykett, the restricted shares will vest upon the first regulatory approval of a Lymphoseek product by either FDA or EMA. All of the restricted shares vest upon the occurrence of a change in control as defined in the restricted stock agreement. If the employment of Dr. Pykett with the Company is terminated for reasons other than a change in control before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreements all restricted shares that have not vested at the effective date of Dr. Pykett's termination shall immediately be forfeited by Dr. Pykett.

(r) Restricted shares granted June 1, 2011. Pursuant to the terms of the restricted stock agreement between the Company and Dr. Tulip, 20,000 of the restricted shares vested upon the completion of the AstraZeneca license agreement on December 9, 2011, 20,000 will vest upon the partnering of Lymphoseek in Europe covering at least four countries, 20,000 will vest upon the partnering of Lymphoseek in Asia covering either Japan or at least two other countries, and 20,000 will vest upon the achievement of annual revenue to the Company from Cardinal Health, Inc. related to Lymphoseek of over $2 million per month for three consecutive months following the receipt of commercial marketing clearance in the U.S., if achieved before the 24th month following such marketing clearance. All of the restricted shares vest upon the occurrence of a change in control as defined in Dr. Tulip's employment agreement, or if Dr. Tulip is terminated without cause as defined in his employment agreement. If the employment of Dr. Tulip with the Company is terminated for reasons other than a change in control or without cause before all of the restricted shares have vested, then pursuant to the terms of the restricted stock agreement all restricted shares that have not vested at the effective date of Dr. Tulip's termination shall immediately be forfeited by Dr. Tulip.

(s) Estimated by reference to the closing market price of the Company's common stock on December 31, 2011, pursuant to Instruction 3 to Item 402(p)(2) of Regulation S-K. The closing price of the Company's common stock

on December 31, 2011, was $2.62.

Options Exercised and Stock Vested

The following table presents, with respect to the Named Executive Officers, certain information about option exercises and restricted stock vested during fiscal 2011.

Options Exercised and Stock Vested Table for Fiscal 2011

	Option Awards			Stock Awards		
Named Executive Officer	Number of Shares Acquired on Exercise	Value Realized on Exercise (a)		Number of Shares Acquired on Vesting	Value Realized on Vesting (a)	
David C. Bupp	1,525,000	$ 5,774,650	(b)	1,000,000	$ 3,576,000	(c),(d)
Mark J. Pykett, V.M.D., Ph.D.	—	—		—	—	
Rodger A. Brown	190,000	488,100	(e)	—	—	
Frederick O. Cope, Ph.D.	—	—		—	—	
Brent L. Larson	120,000	310,300	(f)	—	—	
Thomas H. Tulip, Ph.D.	—	—		20,000	49,980	(g)

(a) Computed using the fair market value of the stock on the date prior to or the date of exercise or vesting, as appropriate, in accordance with our normal practice.

(b) On April 13, 2011, Mr. Bupp exercised options to purchase 1,525,000 shares of common stock at exercise prices ranging from $0.13 to $0.49 per share and a weighted average exercise price of $0.32 per share. After cancelling 637,321 shares of stock to cover the exercise price and related taxes, we issued 887,679 shares of common stock to Mr. Bupp. The market price on the date of exercise was $4.11 per share.

(c) On April 15, 2011, 700,000 shares of Mr. Bupp's restricted stock vested in accordance with the terms of his restricted stock agreements and his separation agreement. The market price of the stock on the vesting date was $4.03 per share.

(d) On August 15, 2011, 300,000 shares of Mr. Bupp's restricted stock vested upon ratification by our stockholders of the amendment to the Company's Amended and Restated 2002 Stock Incentive Plan at the 2011 Annual Meeting of Stockholders, in accordance with the terms of his restricted stock agreement and his separation agreement. The market price on the date prior to vesting was $2.52 per share.

(e) On November 1, 2011, Mr. Brown exercised options to purchase 190,000 shares of common stock at exercise prices ranging from $0.13 to $0.42 per share and a weighted average exercise price of $0.27 per share. After cancelling 80,779 shares of stock to cover the exercise price and related taxes, we issued 109,221 shares of common stock to Mr. Brown. The market price on the date prior to exercise was $2.84 per share.

(f) On November 1, 2011, Mr. Larson exercised options to purchase 120,000 shares of common stock at exercise prices ranging from $0.13 to $0.42 per share and a weighted average exercise price of $0.25 per share. After cancelling 47,287 shares of stock to cover the exercise price and related taxes, we issued 72,713 shares of common stock to Mr. Larson. The market price on the date prior to exercise was $2.84 per share.

(g)

On December 9, 2011, the execution of the license agreement with AstraZeneca caused 20,000 shares of Dr. Tulip's restricted stock to vest in accordance with the terms of his restricted stock agreement. The market price of the stock on the vesting date was $2.50 per share.

Compensation of Non-Employee Directors

Each non-employee director received an annual cash retainer of $25,000 and earned an additional $2,500 per board meeting attended in person or $500 per telephonic board meeting during the fiscal year ended December 31, 2011. The Chairman of the Company's Board of Directors received an additional annual retainer of $12,500, the Chairman of the Audit Committee received an additional annual retainer of $10,000, the Vice Chairman of the Board of Directors received an additional annual retainer of $5,000, and the Chairman of the CNG Committee received an additional annual retainer of $3,750 for their services in those capacities during 2011. Members of all committees of the Company's Board of Directors earned an additional $1,000 per committee meeting, whether attended in person or telephonically. We also reimbursed non-employee directors for travel expenses for meetings attended during 2011.

Each non-employee director also received 17,000 shares of restricted stock as a part of the Company's annual stock incentive grants, in accordance with the provisions of the Navidea Biopharmaceuticals, Inc. Third Amended and Restated 2002 Stock Incentive Plan. The restricted stock granted will vest on the date of approval by FDA of a Phase 3 clinical program for a RIGS technology product or the approval of marketing authorization for a RIGS technology product by EMA. The aggregate number of equity awards outstanding at February 17, 2012 for each Director is set forth in the footnotes to the beneficial ownership table provided in Part III, Item 12 of this Form 10-K. Directors who are also officers or employees of Neoprobe do not receive any compensation for their services as directors.

The following table sets forth certain information concerning the compensation of non-employee Directors for the fiscal year ended December 31, 2011.

Name	(a) Fees Earned or Paid in Cash	(b),(c) Option Awards	(d),(e) Stock Awards	All Other Compensation	Total Compensation
Carl J. Aschinger, Jr. (f)	$ 40,625	$—	$45,033	$ —	$ 85,658
David C. Bupp (g)	31,250	—	—	—	31,250
David C. Bupp (h)	—	—	—	31,825	31,825
Peter F. Drake, Ph.D. (i)	36,563	—	88,043	—	124,606
Brendan A. Ford	59,250	—	45,033	—	104,283
Owen E. Johnson, M.D. (f)	32,250	—	45,033	—	77,283
Jess Emery Jones, M.D. (i)	32,750		88,043	—	120,793
Fred B. Miller (f)	39,000	—	45,033	—	84,033
Eric K. Rowinsky, M.D.	48,500	—	45,033	—	93,533
Eric K. Rowinsky, M.D. (j)	—	92,398	171,540	98,433	362,371
Gordon A. Troup	55,625	—	45,033	—	100,658

(a) Amount represents fees earned during the fiscal year ended December 31, 2011 (i.e., the year to which the service relates). Quarterly retainers and meeting attendance fees are paid during the quarter following the quarter in which they are earned.

(b) Amount represents the aggregate grant date fair value in accordance with FASB ASC Topic 718. Assumptions made in the valuation of stock option awards are disclosed in Note 1(e) of the Notes to the Consolidated Financial Statements in this Form 10-K.

(c) At December 31, 2011, the non-employee directors held an aggregate of 50,000 options to purchase shares of common stock of the Company. Dr. Rowinsky held 30,000 options and Mr. Troup held 20,000 options.

(d) Amount represents the aggregate grant date fair value in accordance with FASB ASC Topic 718. Assumptions made in the valuation of restricted stock awards are disclosed in Note 1(e) of the Notes to the Consolidated Financial Statements in this Form 10-K.

(e) At December 31, 2011, the non-employee directors held an aggregate of 505,000 shares of unvested restricted stock. Mr. Bupp held 300,000 shares of unvested restricted stock, Messrs. Ford and Troup each held 47,000 shares of unvested restricted stock, Drs. Drake and Jones each held 17,000 shares of unvested restricted stock, and Dr. Rowinsky held 77,000 shares of unvested restricted stock.

(f) Mr. Aschinger, Dr. Johnson, and Mr. Miller retired from our Board of Directors effective August 15, 2011, the date of the 2011 Annual Meeting.

(g) Mr. Bupp retired from his position as the Company’s President and Chief Executive Officer and therefore became a non-employee director of the Company effective April 15, 2011.

(h) Following his retirement, Mr. Bupp continued to provide services to the Company under a consulting agreement, earning a total of $31,825 during the year ended December 31, 2011.

(i) Drs. Drake and Jones were appointed to the Company’s Board of Directors effective May 23, 2011.

(j) In addition to his service as a Board member, Dr. Rowinsky provided services to the Company under a consulting agreement. During the year ended December 31, 2011, Dr. Rowinsky earned a total of $98,433 in cash consulting

fees, and was issued 60,000 options to purchase shares of common stock of the Company and 60,000 shares of restricted stock, 30,000 shares of which vested on December 9, 2011 upon the Company’s execution of the AstraZeneca license agreement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Equity Compensation Plan Information

The following table sets forth additional information as of December 31, 2011, concerning shares of our common stock that may be issued upon the exercise of options and other rights under our existing equity compensation plans and arrangements, divided between plans approved by our stockholders and plans or arrangements not submitted to our stockholders for approval. The information includes the number of shares covered by, and the weighted average exercise price of, outstanding options and other rights and the number of shares remaining available for future grants excluding the shares to be issued upon exercise of outstanding options, warrants, and other rights.

	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders[(1)]	3,315,000	$ 1.02	2,351,177
Equity compensation plans not approved by security holders	—	—	—
Total	3,315,000	$ 1.02	2,351,177

(1) Our stockholders ratified the Third Amended and Restated 2002 Stock Incentive Plan (the Plan) at the 2011 Annual Meeting of Stockholders held on August 15, 2011, which (1) increased the total number of shares available for grant under the Plan to 10,000,000 shares; and (2) extended the expiration date for the Plan from March 7, 2012, to March 7, 2015.

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

The following table sets forth, as of February 17, 2012, certain information with respect to the beneficial ownership of shares of our common stock by: (i) each person known to us to be the beneficial owner of more than 5% of our outstanding shares of common stock, (ii) each director or nominee for director of our Company, (iii) each of the Named Executive Officers (see "Executive Compensation – Summary Compensation Table"), and (iv) our directors and executive officers as a group.

Beneficial Owner	**Number of Shares Beneficially Owned (*)**		**Percent of Class (**)**	
Rodger A. Brown	332,554	(a)	(m)	
Frederick O. Cope, Ph.D.	140,358	(b)	(m)	
Peter F. Drake, Ph.D.	10,000	(c)	(m)	
Brendan A. Ford	50,000	(d)	(m)	
Jess Emery Jones, M.D.	—	(e)	(m)	
Brent L. Larson	719,744	(f)	(m)	
Mark J. Pykett, V.M.D., Ph.D.	71,067	(g)	(m)	
Eric K. Rowinsky, M.D.	75,000	(h)	(m)	
Gordon A. Troup	70,000	(i)	(m)	
Thomas H. Tulip, Ph.D.	20,000	(j)	(m)	
All directors and officers as a group (10 persons)	1,488,723	(k)(n)	1.5	%
Platinum Montaur Life Sciences, LLC	4,465,813	(l)	4.7	%

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

(**) Percent of class is calculated on the basis of the number of shares outstanding on February 17, 2012, plus the number of shares the person has the right to acquire within 60 days of February 17, 2012.

(a) This amount includes 223,333 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 45,000 shares of unvested restricted stock and 126,667 shares issuable upon exercise of options which are not exercisable within 60 days.

(b) This amount includes 130,000 shares issuable upon exercise of options which are exercisable within 60 days and 5,358 shares in Dr. Cope's account in the 401(k) Plan, but it does not include 175,000 shares of unvested restricted stock and 242,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(c) This amount does not include 17,000 shares of unvested restricted stock.

(d) This amount does not include 47,000 shares of unvested restricted stock.

(e) This amount does not include 17,000 shares of unvested restricted stock.

(f)

This amount includes 408,750 shares issuable upon exercise of options which are exercisable within 60 days and 95,869 shares in Mr. Larson's account in the 401(k) Plan, but it does not include 125,000 shares of unvested restricted stock and 184,250 shares issuable upon exercise of options which are not exercisable within 60 days.

(g) This amount includes 66,667 shares issuable upon exercise of options which are exercisable within 60 days and 1,100 shares held in an IRA which is owned by Dr. Pykett, but it does not include 650,000 shares of unvested restricted stock and 383,333 shares issuable upon exercise of options which are not exercisable within 60 days.

(h) This amount includes 30,000 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 77,000 shares of unvested restricted stock and 30,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(i) This amount includes 20,000 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 47,000 shares of unvested restricted stock.

(j) This amount does not include 60,000 shares of unvested restricted stock and 273,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(k) This amount includes 878,750 shares issuable upon exercise of options which are exercisable within 60 days, 1,100 shares that are held in an IRA owned by Dr. Pykett, and 101,227 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 1,260,000 shares of unvested restricted stock and 1,239,250 shares issuable upon the exercise of options which are not exercisable within 60 days. The Company itself is the trustee of the Neoprobe 401(k) Plan and may, as such, share investment power over common stock held in such plan. The trustee disclaims any beneficial ownership of shares held by the 401(k) Plan. The 401(k) Plan holds an aggregate total of 644,293 shares of common stock. The 10 persons referenced in this disclosure include each director and named executive officer listed in the table.

(l) Based on information filed on Schedule 13D/A with the Securities and Exchange Commission on April 21, 2011. The number of shares beneficially owned by Platinum-Montaur Life Sciences, LLC (Montaur), 152 W. 57th Street, 54th Floor, New York, NY 10019, does not include 29,701,410 shares of common stock issuable upon conversion of 917 shares of Series B Convertible Preferred Stock, 6,000,000 shares of common stock issuable upon exercise of a Series W Warrant issued to Montaur on December 26, 2007, as amended (the Series W Warrant), 8,333,333 shares of common stock issuable upon exercise of a Series X Warrant issued to Montaur on April 16, 2008 (the Series X Warrant), and 2,400,000 shares of common stock issuable upon exercise of a Series AA Warrant issued to Montaur on July 24, 2009 (the Series AA Warrant). The Certificates of Designation of the Preferred Stock, the Series W Warrant, the Series X Warrant and the Series AA Warrant each provide that the holder of shares of the Preferred Stock, the Series W Warrant, the Series X Warrant and the Series AA Warrant, respectively, may not convert any of the preferred stock or exercise any of the warrants to the extent that such conversion or exercise would result in the holder and its affiliates together beneficially owning more than 9.99% of the outstanding shares of common stock, except on 61 days' prior written notice to Navidea that the holder waives such limitation.

(m) Less than one percent.

(n) The address of all directors and executive officers is c/o Navidea Biopharmaceuticals, Inc., 425 Metro Place North, Suite 450, Dublin, Ohio 43017-1367.

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

Certain Relationships and Related Transactions

We adhere to our Code of Business Conduct and Ethics, which states that no director, officer or employee of Navidea should have any personal interest that is incompatible with the loyalty and responsibility owed to our Company. We do not currently have a written policy regarding related party transactions. When considering whether to enter into a related party transaction, the Board considers a variety of factors including, but not limited to, the nature and type of the proposed transaction, the potential value of the proposed transaction, the impact on the actual or perceived independence of the related party and the potential value to the Company of entering into such a transaction. All proposed transactions with a potential value of greater than $120,000 are approved by the Board.

In July 2007, David C. Bupp, our then-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 extended the term of the $1.0 million Bupp Note to December 31, 2011. In consideration for the Bupp Investors' agreement to extend the term of the Bupp Note, we agreed to provide security for the obligations

evidenced by the amended Bupp Note (the Amended Bupp Note), under the terms of a Security Agreement, dated December 26, 2007, by and between the Company and the Bupp Investors. 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 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. As a result of this exchange transaction, all security interests in the Company’s assets held by the Bupp Investors were extinguished.

During 2011, Mr. Bupp and certain members of his family exercised 810,000 Series V warrants in exchange for issuance of 810,000 shares of our common stock, resulting in gross proceeds of $255,600.

In August 2010, we entered into a Consulting Agreement with Eric K. Rowinsky, M.D. for services related to the development and regulatory strategies regarding Lymphoseek and RIGS, as well as business development assessments and transactions. Dr. Rowinsky's Consulting Agreement was renewed in August 2011. During 2011, we paid Dr. Rowinsky a total of $98,433 in cash consulting fees, and issued 60,000 options to purchase shares of common stock of the Company and 60,000 shares of restricted stock, 30,000 shares of which vested on December 9, 2011 upon the Company's execution of the AstraZeneca license agreement.

Director Independence

Our Board of Directors has adopted the definition of "independence" as described under the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley) Section 301, Rule 10A-3 under the Securities Exchange Act of 1934 (the Exchange Act) and Section 803A of the NYSE Amex Company Guide. Our Board of Directors has determined that Messrs. Ford and Troup, and Drs. Drake and Jones, meet the independence requirements. Mr. Aschinger, Dr. Johnson, and Mr. Miller met the independence requirements prior to their retirement effective August 15, 2011.

Item 14. Principal Accountant Fees and Services

Audit Fees.). The aggregate fees billed and expected to be billed for professional services rendered by BDO USA, LLP for the audit of the Company's annual consolidated financial statements for the 2011 fiscal year, the audit of the Company's internal control over financial reporting as of December 31, 2011, the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2011 fiscal year, consents related to the Company's registration statements filed during the 2011 fiscal year, and consulting services related to the Company's sale of the GDS Business during the 2011 fiscal year were $256,617 (including direct engagement expenses). The aggregate fees billed and expected to be billed for professional services rendered by BDO USA, LLP for the audit of the Company's annual consolidated financial statements for the 2010 fiscal year, the audit of the Company's internal control over financial reporting as of December 31, 2010, the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2010 fiscal year, consents related to the Company's registration statements filed during the 2010 fiscal year, and consulting services related to the Company's modification of certain debt and equity instruments during the 2010 fiscal year were $267,171 (including direct engagement expenses).

Audit-Related Fees. No fees were billed by BDO USA, LLP for audit-related services for the 2011 or 2010 fiscal years.

Tax Fees. The aggregate fees billed and expected to be billed for tax-related services rendered by BDO USA, LLP for the IRC Section 382 study and the review of the Company's tax returns for the 2010 tax year during the 2011 fiscal year were $29,285 (including direct engagement expenses). The aggregate fees billed and expected to be billed for

tax-related services rendered by BDO USA, LLP for consulting services related to the Section 48D tax credit and the review of the Company's tax returns for the 2009 tax year during the 2010 fiscal year were $23,410 (including direct engagement expenses).

All Other Fees. No fees were billed by BDO USA, LLP for services other than the audit, audit-related and tax services for the 2011 or 2010 fiscal years.

Pre-Approval Policy. The Audit Committee is required to pre-approve all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for the Company by its independent auditor or other registered public accounting firm, subject to the *de minimis* exceptions for permitted non-audit services described in Section 10A(i)(1)(B) of the Securities Exchange Act of 1934 that are approved by the Audit Committee prior to completion of the audit. The Audit Committee, through the function of the Chairman, has given general pre-approval for 100% of specified audit, audit-related, tax and other services.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Navidea Biopharmaceuticals, Inc., as corrected February 18, 1994, and amended June 27, 1994, July 25, 1995, June 3, 1996, March 17, 1999, May 9, 2000, June 13, 2003, July 29, 2004, June 22, 2005, November 20, 2006, December 26, 2007, April 30, 2009, July 27, 2009, August 2, 2010, and January 5, 2012).*
3.2	Certificate of Ownership Merging Neoprobe Name Change, Inc. into Neoprobe Corporation, effective January 5, 2012, as filed with the Delaware Secretary of State (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed December 21, 2011, and incorporated herein by reference).
3.3	Amended and Restated By-Laws dated July 21, 1993, as amended July 18, 1995, May 30, 1996 and July 26, 2007 (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed August 3, 2007, and incorporated herein by reference).
4.1	Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series B Cumulative Convertible Preferred Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 28, 2010).
4.2	Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series C 10% Cumulative Convertible Preferred Stock (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed June 28, 2010).
10.1	Navidea Biopharmaceuticals, Inc. Third Amended and Restated 2002 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 15, 2011).
10.2	Form of Stock Option Agreement under the Navidea Biopharmaceuticals, Inc. Third Amended and Restated 2002 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 21, 2006).
10.3	Form of Restricted Stock Award and Agreement under the Third Amended and Restated 2002 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed January 9, 2008).
10.4	Form of Employment Agreement between the Company and each of Drs. Mark J. Pykett, Frederick O. Cope and Thomas H. Tulip, and Messrs. Brent L. Larson and Rodger A Brown. This agreement is one of five substantially identical employment agreements and is accompanied by a schedule which identifies material details in which each individual agreement differs from the form filed herewith (incorporated by reference to the Company's Current Report on Form 8-K filed December 27, 2010).

10.5	Schedule identifying material differences between the employment agreements incorporated by reference as Exhibit 10.4 to this Annual Report on Form 10-K.*

10.6	Technology Transfer Agreement, dated July 29, 1992, between the Company and The Dow Chemical Corporation (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.10 to the Company's Form S-1 filed October 15, 1992).
10.7	Cooperative Research and Development Agreement between the Company and the National Cancer Institute (incorporated by reference to Exhibit 10.3.31 to the Company's September 30, 1995, Form 10–QSB).
10.8	License, dated May 1, 1996, between the Company and The Dow Chemical Company (incorporated by reference to Exhibit 10.3.45 to the Company's June 30, 1996, Form 10–QSB).
10.9	License Agreement, dated May 1, 1996, between the Company and The Dow Chemical Company (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.3.46 to the Company's June 30, 1996, Form 10–QSB).
10.10	License Agreement, dated January 30, 2002, between the Company and the Regents of the University of California, San Diego, as amended on May 27, 2003 and February 1, 2006 (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-KSB filed March 31, 2006).
10.11	Evaluation License Agreement, dated March 31, 2005, between the Company and the Regents of the University of California, San Diego (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-KSB filed March 31, 2006).
10.12	Product Supply Agreement between the Company and TriVirix International, Inc., dated February 5, 2004 (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.17 to the Company's December 31, 2004 Form 10-KSB).
10.13	Supply and Distribution Agreement, dated November 15, 2007, by and between the Company and Cardinal Health 414, LLC (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 21, 2007).
10.14	Manufacture and Supply Agreement, dated November 30, 2009, between the Company and Reliable Biopharmaceutical Corporation (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.1 to the Company's June 30, 2010 Form 10-Q).
10.15	Series V Warrant to Purchase Common Stock issued to David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed July 9, 2007).

10.16	Registration Rights Agreement, dated July 3, 2007, by and among the Company and David C. Bupp, Cynthia B. Gochoco and Walter H. Bupp, as joint tenants with right of survivorship (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed July 9, 2007).
10.17	Securities Purchase Agreement, dated as of December 26, 2007, by and between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 2, 2008).
10.18	Amendment and Waiver for Securities Purchase Agreement, dated April 16, 2008, between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 18, 2008).
10.19	Agreement Modifying the Interest and Dividend Payment Dates of the Company's Series A and B Promissory Notes and Series A Preferred Stock, and Exercise and Conversion Price Adjustment Provisions of the Company's Series X and Y Warrants and Series A Preferred Stock, dated March 31, 2009, by and between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 6, 2009).
10.20	Securities Amendment and Exchange Agreement, dated July 24, 2009, by and between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 29, 2009).
10.21	Amended and Restated Series W Warrant to Purchase Shares of Common Stock of the Company issued to Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed July 29, 2009).
10.22	Amended and Restated Series X Warrant to Purchase Shares of Common Stock of the Company issued to Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed July 29, 2009).
10.23	Series AA Warrant to Purchase Shares of Common Stock of the Company issued to Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed July 29, 2009).
10.24	Registration Rights Agreement, dated December 26, 2007, between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed January 2, 2008).
10.25	Second Amendment to Registration Rights Agreement, dated April 16, 2008, between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 18, 2008).
10.26	Third Amendment to Registration Rights Agreement, dated July 10, 2008, between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.55 to pre-effective amendment No. 2 to the Company's Registration Statement on Form S-1, filed July 24, 2008, Registration file No. 333-150650).
10.27	

	Fourth Amendment to Registration Rights Agreement, dated December 5, 2008, between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 9, 2008).
10.28	Fifth Amendment to Registration Rights Agreement, dated December 21, 2009, between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 22, 2009).

10.29	Securities Exchange Agreement, dated June 22, 2010, by and between the Company and Platinum-Montaur Life Sciences, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 28, 2010).
10.30	Securities Exchange Agreement, dated June 22, 2010, by and among the Company, and David C. Bupp and Cynthia B. Gochoco, both individually and as co-executors of the Estate of Walter H. Bupp (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 28, 2010).
10.31	Letter Agreement, dated November 7, 2010, by and between the Company and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed November 12, 2010).
10.32	Securities Purchase Agreement, dated November 7, 2010, by and among the Company and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 12, 2010).
10.33	Form of Series CC Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 12, 2010).
10.34	Form of Series DD Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 12, 2010).
10.35	Form of Series EE Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed November 12, 2010).
10.36	Navidea Biopharmaceuticals, Inc. 2011 Cash Bonus Plan (incorporated by reference to the Company's Current Report on Form 8-K filed December 27, 2010).
10.37	Separation Agreement and Release, dated March 30, 2011, by and between the Company and David C. Bupp (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 1, 2011).
10.38	Consulting Agreement, dated March 30, 2011, by and between the Company and David C. Bupp (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 1, 2011).
10.39	Employment Agreement, effective April 15, 2011, by and between the Company and Mark J. Pykett (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed April 1, 2011).
10.40	Relocation Agreement, dated March 30, 2011, by and between the Company and Mark J. Pykett (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed April 1, 2011).
10.41	Settlement Agreement, dated April 18, 2011, by and among Platinum-Montaur Life Sciences, LLC, Platinum Partners Value Arbitrage Fund, L.P. and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 18, 2011).
10.42	Asset Purchase Agreement, dated May 24, 2011, by and between Devicor Medical Products, Inc. and the Company (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the SEC) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed July 19, 2011).

10.43	Employment Agreement, dated June 1 2011, between the Company and Thomas H. Tulip, Ph.D (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 6, 2011).
10.44	Consulting Services Agreement, dated August 3, 2011, by and between the Company and Eric K. Rowinsky, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 4, 2011).
10.45	License Agreement, dated December 9, 2011, by and between AstraZeneca AB and the Company (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the United States Securities and Exchange Commission) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 15, 2011).
10.46	Loan and Security Agreement, dated December 29, 2011, by and between the Company and Hercules Technology II, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 5, 2012).
10.47	Series GG Warrant to Purchase Common Stock of the Company issued to Hercules Technology II, L.P. on December 29, 2011 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 5, 2012).
21.1	Subsidiaries of the registrant.*
23.1	Consent of BDO USA, LLP.*
24.1	Power of Attorney.*
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.*
32.2	Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.*

* Filed herewith.

SIGNATURES

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

Dated: March 6, 2012

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)

By: /s/ Mark J. Pykett
Mark J. Pykett
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Mark J. Pykett Mark J. Pykett	Director, President and Chief Executive Officer (principal executive officer)	February 16, 2012
/s/ Brent L. Larson* Brent L. Larson	Senior Vice President and Chief Financial Officer (principal financial officer)	February 16, 2012
/s/ Gordon A. Troup* Gordon A. Troup	Chairman, Director	February 16, 2012
/s/ Peter F. Drake* Peter F. Drake	Director	February 16, 2012
/s/ Brendan A. Ford* Brendan A. Ford	Director	February 16, 2012
/s/ Jess Emery Jones* Jess Emery Jones	Director	February 16, 2012
/s/ Eric K. Rowinsky* Eric K. Rowinsky	Director	February 16, 2012

*By: /s/ Mark J. Pykett
Mark J. Pykett, Attorney-in-fact

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

NAVIDEA BIOPHARMACEUTICALS, INC.

(formerly Neoprobe Corporation)

FORM 10-K ANNUAL REPORT

As of December 31, 2011 and 2010

and for Each of the

Three Years in the Period Ended

December 31, 2011

FINANCIAL STATEMENTS

NAVIDEA BIOPHARMACEUTICALS, INC. and SUBSIDIARIES

(formerly Neoprobe Corporation)

Index to Financial Statements

Consolidated Financial Statements of Navidea Biopharmaceuticals, Inc.

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Report of Independent Registered Public Accounting Firm

Board of Directors

Navidea Biopharmaceuticals, Inc.

Dublin, Ohio

We have audited the accompanying consolidated balance sheets of Navidea Biopharmaceuticals, Inc. (formerly Neoprobe Corporation) as of December 31, 2011 and 2010 and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Navidea Biopharmaceuticals, Inc. at December 31, 2011 and 2010, and the results of its operations and cash flows for each of the three years in the period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Navidea Biopharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control−Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 6, 2012 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Chicago, Illinois

March 6, 2012

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Navidea Biopharmaceuticals, Inc. and Subsidiaries (formerly Neoprobe Corporation)

Consolidated Balance Sheets

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash	$ 28,644,004	$ 6,420,506
Accounts receivable, net	15,794	137,958
Inventory	821,549	632,000
Prepaid expenses and other	554,544	257,899
Assets associated with discontinued operations, current	10,630	2,784,640
Total current assets	30,046,521	10,233,003
Property and equipment	1,441,229	1,366,105
Less accumulated depreciation and amortization	977,960	960,726
	463,269	405,379
Patents and trademarks	106,592	63,643
Less accumulated amortization	21,171	21,171
	85,421	42,472
Other assets	598,709	7,421
Assets associated with discontinued operations	—	174,463
Total assets	$ 31,193,920	$ 10,862,738

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries (formerly Neoprobe Corporation)

Consolidated Balance Sheets, continued

	December 31, 2011	December 31, 2010
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$681,754	$1,357,796
Accrued liabilities and other	2,087,722	1,014,130
Note payable to finance company	—	62,411
Derivative liabilities, current	568,930	405,524
Liabilities associated with discontinued operations, current	10,064	1,104,578
Total current liabilities	3,348,470	3,944,439
Note payable to investor, net of discount of $543,612	6,456,388	—
Derivative liabilities	—	2,077,799
Liabilities associated with discontinued operations	—	672,924
Other liabilities	257,315	35,831
Total liabilities	10,062,173	6,730,993
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 9,083 Series B shares and 1,000 Series C shares issued and outstanding at December 31, 2011, and 10,000 Series B shares and 1,000 Series C shares issued and outstanding at December 31, 2010	10	11
Common stock; $.001 par value; 200,000,000 shares authorized; 95,398,961 and 86,319,913 shares issued and outstanding at December 31, 2011 and 2010, respectively	95,399	86,320
Additional paid-in capital	266,393,645	254,915,713
Accumulated deficit	(245,357,307)	(250,870,299)
Total stockholders' equity	21,131,747	4,131,745
Total liabilities and stockholders' equity	$31,193,920	$10,862,738

See accompanying notes to consolidated financial statements.

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Navidea Biopharmaceuticals, Inc. and Subsidiaries (formerly Neoprobe Corporation)

Consolidated Statements of Operations and Comprehensive Income (Loss)

	Years Ended December 31,		
	2011	2010	2009
Grant revenue	$597,729	$617,392	$—
Operating expenses:			
Research and development	15,154,365	8,941,046	4,379,614
Selling, general and administrative	9,547,779	4,353,136	3,028,500
Total operating expenses	24,702,144	13,294,182	7,408,114
Loss from operations	(24,104,415)	(12,676,790)	(7,408,114)
Other income (expense):			
Interest income	25,755	8,804	18,749
Interest expense	(13,330)	(554,988)	(1,533,047)
Change in derivative liabilities	(952,375)	(1,336,234)	(18,132,274)
Loss on extinguishment of debt	—	(41,717,380)	(16,240,592)
Other	(3,211)	32,594	(3,422)
Total other expense, net	(943,161)	(43,567,204)	(35,890,586)
Loss before income taxes	(25,047,576)	(56,243,994)	(43,298,700)
Benefit from income taxes	7,880,143	2,134,903	1,255,613
Loss from continuing operations	(17,167,433)	(54,109,091)	(42,043,087)
Discontinued operations, net of tax effect:			
Gain on sale	19,450,891	—	—
Impairment loss	—	—	(1,131,123)
Income from operations	3,329,534	4,144,223	3,568,490
Net income (loss)	5,612,992	(49,964,868)	(39,605,720)
Preferred stock dividends	(100,000)	(8,206,745)	(240,000)
Income (loss) attributable to common stockholders	$5,512,992	$(58,171,613)	$(39,845,720)
Income (loss) per common share (basic and diluted):			
Continuing operations	$(0.17)	$(0.77)	$(0.57)
Discontinued operations	$0.23	$0.05	$0.03
Attributable to common stockholders	$0.06	$(0.72)	$(0.54)

Weighted average shares outstanding:			
Basic and diluted	90,509,326	80,726,498	73,771,871
Net income (loss)	$5,612,992	$(49,964,868)	$(39,605,720)
Unrealized loss on available-for-sale securities	—	—	(1,383)
Comprehensive income (loss)	5,612,992	(49,964,868)	(39,607,103)
Preferred stock dividends	(100,000)	(8,206,745)	(240,000)
Comprehensive income (loss) attributable to common stockholders	$5,512,992	$(58,171,613)	$(39,847,103)

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries (formerly Neoprobe Corporation)

Consolidated Statements of Stockholders' Equity (Deficit)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Total
Balance, December 31, 2008	—	$—	70,862,641	$70,863	$145,742,044	$(148,840,015)	$1,383	$(3,025,725)
Effect of adopting new provisions of FASB ASC Topic 815	—	—	—	—	(8,948,089)	(4,012,951)	—	(12,961,040)
Issued restricted stock to employees and directors	—	—	1,260,000	1,260	—	—	—	1,260
Cancelled restricted stock	—	—	(9,000)	(9)	9	—	—	—
Issued stock to 401(k) plan	—	—	80,883	81	33,392	—	—	33,473
Issued stock upon exercise of warrants	—	—	6,948,507	6,949	6,534,985	—	—	6,541,934
Issued stock upon exercise of stock options	—	—	400,441	400	124,216	—	—	124,616
Issued stock in payment of interest on convertible debt and dividends on convertible preferred stock	—	—	1,393,239	1,393	1,029,940	—	—	1,031,333
Paid preferred stock issuance costs	—	—	—	—	(6,323)	—	—	(6,323)
Paid common stock issuance costs	—	—	—	—	(207,000)	—	—	(207,000)
	—	—	—	—	37,999,312	—	—	37,999,312

Effect of change in terms of notes payable, preferred stock and warrants								
Stock compensation expense	—	—	—	—	445,411	—	—	445,411
Preferred stock dividends	—	—	—	—	—	(240,000)	—	(240,000)
Net loss	—	—	—	—	—	(39,605,720)	—	(39,605,720)
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(1,383)	(1,383)
Balance, December 31, 2009	—	—	80,936,711	80,937	182,747,897	(192,698,686)	—	(9,869,852)
Issued stock in payment of interest on convertible debt and dividends on convertible preferred stock	—	—	347,832	348	476,319	—	—	476,667
Issued stock upon exercise of options, net of costs	—	—	350,156	350	(64,055)	—	—	(63,705)
Issued stock in connection with stock purchase agreement, net of costs	—	—	660,541	661	776,797	—	—	777,458
Issued stock to 401(k) plan	—	—	53,499	53	40,570	—	—	40,623
Issued Series B and Series C convertible preferred stock, net of costs	11,000	11	—	—	64,636,810	—	—	64,636,821
Cancelled restricted stock	—	—	(4,500)	(5)	5	—	—	—
Issued restricted stock	—	—	660,000	660	—	—	—	660
Issued warrants in connection with consulting agreement	—	—	—	—	279,367	—	—	279,367

Issued stock upon exercise of warrants and other	—	—	157,778	158	316,660	—	—	316,818
Issued common stock and warrants in connection with direct offering, net of costs	—	—	3,157,896	3,158	4,306,793	—	—	4,309,951
Effect of change in terms of warrants	—	—	—	—	800,878	—	—	800,878
Stock compensation expense	—	—	—	—	597,672	—	—	597,672
Preferred stock dividends, including deemed dividends	—	—	—	—	—	(8,206,745)	—	(8,206,745)
Net loss	—	—	—	—	—	(49,964,868)	—	(49,964,868)
Balance, December 31, 2010	11,000	11	86,319,913	86,320	254,915,713	(250,870,299)	—	4,131,745

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries (formerly Neoprobe Corporation)

Consolidated Statements of Stockholders' Equity (Deficit), continued

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Total
Balance, December 31, 2010	11,000	11	86,319,913	86,320	254,915,713	(250,870,299)	—	4,131,745
Issued restricted stock	—	—	872,000	872	—	—	—	872
Cancelled restricted stock	—	—	(686,000)	(686)	90	—	—	(596)
Issued stock to 401(k) plan	—	—	35,233	35	61,936	—	—	61,971
Issued stock upon exercise of warrants, net	—	—	4,026,552	4,027	8,323,163	—	—	8,327,190
Issued stock upon exercise of stock options, net of related income tax withholdings	—	—	1,832,673	1,832	(2,500,055)	—	—	(2,498,223)
Effect of change in terms of warrants	—	—	—	—	1,978,818	—	—	1,978,818
Conversion of Series B preferred stock to common stock	(917)	(1)	2,998,590	2,999	(2,998)	—	—	—
Effect of beneficial conversion feature of promissory note	—	—	—	—	24,888	—	—	24,888
Stock compensation expense	—	—	—	—	3,592,090	—	—	3,592,090
Preferred stock dividends	—	—	—	—	—	(100,000)	—	(100,000)
Net income	—	—	—	—	—	5,612,992	—	5,612,992

Balance, December 31, 2011	10,083	$ 10	95,398,961	$95,399	$266,393,645	$(245,357,307)	$ —	$21,131,747

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries (formerly Neoprobe Corporation)

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2011	2010	2009
Cash flows from operating activities:			
Net income (loss)	$5,612,992	$(49,964,868)	$(39,605,720)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization of equipment	175,296	215,462	202,703
Amortization of intangible assets	1,248	7,998	131,046
Loss on disposal and abandonment of assets	18,645	7,476	18,794
Amortization of debt discount and debt offering costs	3,805	16,109	428,060
Issuance of common stock in payment of interest and dividends	—	476,667	791,333
Stock compensation expense	3,592,090	597,672	445,411
Change in derivative liabilities	952,375	1,336,234	18,132,274
Loss on extinguishment of debt	—	41,717,380	16,240,592
Issuance of warrants in connection with consulting agreement	—	279,367	—
Gain on sale of GDS Business	(26,173,805)	—	—
Impairment loss on Cardiosonix	—	—	1,713,822
Other	61,971	40,623	33,473
Change in operating assets and liabilities:			
Accounts receivable	(219,021)	(707,914)	296,813
Inventory	(53,289)	(381,382)	(653,043)
Prepaid expenses and other assets	(40,204)	39,232	105,262
Accounts payable	(538,666)	759,411	38,146
Accrued liabilities and other liabilities	487,055	157,899	121,277
Deferred revenue	109,503	232,866	77,704
Net cash used in operating activities	(16,010,005)	(5,169,768)	(1,482,053)
Cash flows from investing activities:			
Maturities of available-for-sale securities	—	—	494,000
Purchases of equipment	(183,830)	(366,629)	(96,331)
Proceeds from sales of equipment	1,000	—	251
Proceeds from sale of GDS Business, net	30,159,527	—	—
Payment of transaction costs to sell GDS Business	(2,765,932)	—	—
Patent and trademark costs	(52,504)	(32,111)	(71,344)
Net cash provided by (used in) investing activities	27,158,261	(398,740)	326,576
Cash flows from financing activities:			
Proceeds from issuance of common stock	7,198,373	7,092,163	3,641,010
Payment of tax withholdings related to stock-based compensation	(2,762,710)	(133,153)	(24,134)
Payment of stock issuance costs	—	(478,111)	(219,867)
Payment of preferred stock dividends	(100,000)	(111,389)	—
Proceeds from notes payable	7,000,000	—	—

Payment of debt issuance costs	(189,390)	—	(20,183)
Payment of notes payable	(62,411)	(8,710)	(137,857)
Payments under capital leases	(8,620)	(11,628)	(9,487)
Net cash provided by financing activities	11,075,242	6,349,172	3,229,482
Net increase in cash	22,223,498	780,664	2,074,005
Cash, beginning of year	6,420,506	5,639,842	3,565,837
Cash, end of year	$28,644,004	$6,420,506	$5,639,842

See accompanying notes to consolidated financial statements.

Notes to the Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

a. **Organization and Nature of Operations:** Navidea Biopharmaceuticals, Inc. (formerly Neoprobe Corporation; Navidea, the Company, or we), a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. We are currently developing three radiopharmaceutical agent platforms. The first, Lymphoseek®, is intended to be used in determining the spread of certain solid tumor cancers into the lymphatic system. The second, AZD4694, is intended to be used in the imaging and evaluation of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD). The third, RIGScan™, is intended to be used to help surgeons locate cancerous or disease-involved tissue during colorectal cancer surgeries. All of these drug products are still in development and must be cleared for marketing by the appropriate regulatory bodies before they can be sold in any markets.

Prior to August 2011, we also manufactured a line of gamma radiation detection equipment used in the application of sentinel lymph node biopsy (SLNB). From July 2010 through August 2011, our gamma detection device products were marketed throughout most of the world through a distribution arrangement with 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 biopsy business, including an assignment of the distribution agreement with the Company. As disclosed below, we sold our gamma detection device line of business (the GDS Business) to Devicor in August 2011. Prior to the disposal of the GDS Business, 96%, 96%, and 92% of net sales were made to Devicor or EES for the years ended December 31, 2011, 2010 and 2009, respectively.

In January 2005 we formed a new corporation, Cira Biosciences, Inc. (Cira Bio), to explore the development of patient-specific cellular therapies that have shown positive patient responses in a variety of clinical settings. Cira Bio is combining our activated cellular therapy (ACT) technology for patient-specific oncology treatment with similar technology licensed from Cira LLC, a privately held company, for treating viral and autoimmune diseases. Navidea owns approximately 90% of the outstanding shares of Cira Bio with the remaining shares being held by the principals of Cira LLC.

In July 2011, we established a European business unit, Navidea Biopharmaceuticals Limited, to address international development and commercialization needs for our technologies, including Lymphoseek. Navidea owns 100% of the outstanding shares of Navidea Biopharmaceuticals Limited.

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

In May 2011, the Company's Board of Directors approved the sale (the Asset Sale) of the GDS Business to Devicor and the Company executed an Asset Purchase Agreement (APA) with Devicor dated May 24, 2011. Our stockholders approved the Asset Sale at our Annual Meeting of Stockholders on August 15, 2011, and the Asset Sale closed on August 17, 2011 consistent with the terms of the APA. Under the terms of the APA, we sold the assets and assigned certain liabilities that were primarily related to the GDS Business. In December 2011, we disposed of the extended warranty contracts related to the GDS Business, which were outstanding as of the date of the sale of the GDS Business but were not included in the August 2011 transaction. Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the GDS Business as a discontinued operation. Cash flows associated with the operation of the GDS Business have been combined within operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows. See Note 2.

In August 2009, the Company's Board of Directors decided to discontinue the operations of, and 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. Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect Cardiosonix as a discontinued operation. Cash flows associated with the operation of Cardiosonix have been combined within operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows. See Note 2.

Notes to the Consolidated Financial Statements

c. **Use of Estimates:** The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

d. **Financial Instruments and Fair Value:** The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value, giving the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

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

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

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

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. In determining the appropriate levels, we perform a detailed analysis of the assets and liabilities whose fair value is measured on a recurring basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3. See Note 3.

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

(1) Cash, accounts receivable, accounts payable, and accrued liabilities: The carrying amounts approximate fair value because of the short maturity of these instruments.

(2) Note payable to finance company: The fair value of our debt is estimated by discounting the future cash flows at rates currently offered to us for similar debt instruments of comparable maturities by banks or finance companies. We had no notes payable to finance companies at December 31, 2011. At December 31, 2010, the carrying value of this instrument approximated fair value.

(3) Note payable to investor: The carrying value of our debt at December 31, 2011 is presented as the face amount of the note less unamortized discounts. At December 31, 2011, the carrying value of the note payable to investor approximates fair value based on the proximity of the loan date to year-end. See Note 9.

(4) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. The assumptions used to calculate fair value as of December 31, 2011 and 2010 include volatility, risk-free rate and expected dividends. In addition, we considered non-performance risk and determined that such risk is minimal. Unrealized gains and losses on the derivatives are classified in other expenses as a change in derivative liabilities in the statements of operations. See Note 11.

Notes to the Consolidated Financial Statements

e. **Stock-Based Compensation:** At December 31, 2011, we have instruments outstanding under two stock-based compensation plans; the 1996 Stock Incentive Plan (the 1996 Plan), and the Third Amended and Restated 2002 Stock Incentive Plan (the 2002 Plan). Currently, under the 2002 Plan, we may grant incentive stock options, nonqualified stock options, and restricted stock awards to full-time employees and directors, and nonqualified stock options and restricted stock awards may be granted to our consultants and agents. Total shares authorized under each plan are 1.5 million shares and 10 million shares, respectively. Although instruments are still outstanding under the 1996 Plan, the plan has expired and no new grants may be made from it. Under both plans, the exercise price of each option is greater than or equal to the closing market price of our common stock on the day prior to the date of the grant.

Stock options granted under the 1996 Plan and the 2002 Plan generally vest on an annual basis over one to four years. Outstanding stock options under the plans, if not exercised, generally expire ten years from their date of grant or 90 days from the date of an optionee's separation from employment with the Company. We issue new shares of our common stock upon exercise of stock options.

Stock-based payments to employees and directors, including grants of stock options, are recognized in the consolidated statement of operations based on their estimated fair values. The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. Expected volatilities are based on the Company's historical volatility, which management believes represents the most accurate basis for estimating expected future volatility under the current circumstances. Navidea uses historical data to estimate forfeiture rates. The expected term of stock options granted is based on the vesting period and the contractual life of the options. The risk-free rate is based on the U.S. Treasury yield in effect at the time of the grant. The assumptions used to calculate fair value for the years ended December 31, 2011, 2010 and 2009 are noted in the following table:

	2011	2010	2009
Expected volatility	64%-71 %	61%-68 %	73%-91 %
Weighted-average volatility	69 %	66 %	81 %
Expected dividends	—	—	—
Expected term (in years)	5.3-6.3	6.0-6.3	5.5-6.0
Risk-free rate	1.3%-2.4%	1.7%-2.4%	1.8%-2.7%

Compensation cost arising from stock-based awards is recognized as expense using the straight-line method over the vesting period. Restricted shares generally vest upon occurrence of a specific event or achievement of goals as defined in the grant agreements. As a result, we record compensation expense related to grants of restricted stock based on management's estimates of the probable dates of the vesting events. See Note 4.

f. **Cash and Cash Equivalents:** Cash equivalents are highly liquid instruments such as U.S. Treasury bills, bank certificates of deposit, corporate commercial paper and money market funds which have maturities of less than 3 months from the date of purchase. The Company held no cash equivalents at December 31, 2011 or 2010.

g. **Inventory:** All components of inventory are valued at the lower of cost (first-in, first-out) or market. We adjust inventory to market value when the net realizable value is lower than the carrying cost of the inventory. Market value is determined based on estimated sales activity and margins. From time to time, we capitalize certain inventory costs associated with our Lymphoseek product prior to regulatory approval and product launch based on management's judgment of probable future commercial use and net realizable value of the inventory. We could be required to permanently write down previously capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the inventory previously expensed becomes available and is used for commercial sale. See Note 6.

Notes to the Consolidated Financial Statements

h. **Property and Equipment:** Property and equipment are stated at cost, less accumulated depreciation and amortization. Property and equipment under capital leases are stated at the present value of minimum lease payments. Depreciation is computed using the straight-line method over the estimated useful lives of the depreciable assets ranging from 3 to 7 years, and includes amortization related to equipment under capital leases, which is amortized over the shorter of the estimated useful life of the leased asset or the term of the lease. Maintenance and repairs are charged to expense as incurred, while renewals and improvements are capitalized. See Note 7.

i. **Intangible Assets:** Intangible assets consist primarily of patents and trademarks. Intangible assets are stated at cost, less accumulated amortization. Patent costs are amortized using the straight-line method over the estimated useful lives of the patents of approximately 5 to 15 years. Patent application costs are deferred pending the outcome of patent applications. Costs associated with unsuccessful patent applications and abandoned intellectual property are expensed when determined to have no recoverable value. We evaluate the potential alternative uses of all intangible assets, as well as the recoverability of the carrying values of intangible assets, on a recurring basis.

j. **Impairment or Disposal of Long-Lived Assets:** Long-lived assets and certain identifiable intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. See Notes 2 and 7.

k. **Other Assets:** We defer costs associated with the issuance of notes payable and amortize those costs over the period of the notes using the effective interest method. In 2011 and 2009, we incurred $593,000 and $20,000, respectively, of debt issuance costs related to notes payable. During 2011, 2010 and 2009, we recorded amortization of $2,000, $4,000 and $69,000, respectively, of deferred debt issuance costs. During 2009, we expensed an additional $524,000 of debt issuance costs as a result of debt modification activities. Other assets at December 31, 2011 include deferred debt issuance costs of $591,000. The Company had no deferred debt issuance costs at December 31, 2010. See Note 10.

l. **Derivative Instruments:** Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated from the debt instrument and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. Derivative liabilities with expiration dates within one year are classified as current, while those with expiration dates in more than one year are classified as long term. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. See Note 11.

m.

Revenue Recognition: We currently generate revenue primarily 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.

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

o. **Income Taxes:** Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2011 and 2010. Estimated tax liabilities of $6.7 million related to the gain on the sale of discontinued operations and $1.2 million related to income from discontinued operations were fully offset by an estimated tax benefit of $7.9 million related to the loss from continuing operations during 2011. Estimated tax liabilities of $2.1 million related to income from discontinued operations were fully offset by an estimated tax benefit of $2.1 million related to the loss from continuing operations during 2010. An estimated tax benefit of $583,000 related to the impairment loss for discontinued operations and estimated tax liabilities of $1.8 million related to income from discontinued operations were fully offset by an estimated tax benefit of $1.3 million related to the loss from continuing operations during 2009. See Note 13.

Notes to the Consolidated Financial Statements

Current accounting standards include guidance on the accounting for uncertainty in income taxes recognized in the financial statements. Such standards also prescribe a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company believes that the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of December 31, 2011 or 2010 and we do not expect any significant changes in the next twelve months. Should we need to accrue interest or penalties on uncertain tax positions, we would recognize the interest as interest expense and the penalties as a selling, general and administrative expense. As of December 31, 2011, tax years 2008-2011 remained subject to examination by federal and state tax authorities.

p. **Recent Accounting Developments:** In May 2011, the Financial Accounting Standards Board (FASB) and International Accounting Standards Board (IASB) issued Accounting Standards Update (ASU) No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs (ASU 2011-04). ASU 2011-04 created a uniform framework for applying fair value measurement principles for companies around the world and clarified existing guidance in US GAAP. ASU 2011-04 is effective for interim and annual reporting periods beginning after December 15, 2011 and shall be applied prospectively. We do not expect ASU 2011-04 to have a material effect on our consolidated financial statements, however, it may result in additional disclosures.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (ASU 2011-05), as amended by ASU No. 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12). The ASUs increase the prominence of items reported in other comprehensive income (OCI) by eliminating the option to present OCI as part of the statement of changes in stockholders' equity. The amendments require companies to present all non-owner changes in stockholders' equity, either as one continuous statement or as two separate but consecutive statements. The ASUs do not change the current option for presenting components of OCI gross of the effect of income taxes, provided that such tax effects are presented in the statement in which OCI is presented or disclosed in the notes to the financial statements. Additionally, the standard does not affect the calculation or reporting of earnings per share. The amendments are effective for interim and annual reporting periods beginning after December 15, 2011 and are to be applied retrospectively, with early adoption permitted. The Company adopted the provisions of ASU 2011-05 early which only impacted the presentation on the statements of operations and comprehensive income (loss). ASU 2011-12 also only impacts presentation and will have no effect on our financial position or results of operations.

q. Reclassification: Certain prior-year amounts have been reclassified to conform to the current-year presentation.

2. Discontinued Operations

In August 2009, the Company's Board of Directors decided to discontinue the operations of, and 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 achievements related to our other device product and drug development initiatives. We have not received significant expressions of interest in the Cardiosonix business; however, we are obligated to continue to service and support the Cardiosonix devices through 2013. As such, while we continue to wind down our activities in this area, we expect to continue to generate minimal revenues and incur minimal expenses related to our blood flow measurement device business until a final shutdown of operations or a sale of the business unit is completed.

Notes to the Consolidated Financial Statements

In August 2011, we completed the sale of the GDS Business to Devicor under the terms of the APA that was signed in May 2011. On August 17, 2011, Devicor made an initial cash payment to us of $30.0 million, assumed certain liabilities of the Company associated with the GDS Business as specified in the APA, and agreed to make royalty payments to us of up to an aggregate maximum amount of $20.0 million based on the net revenue attributable to the GDS Business over the course of the next six fiscal years beginning in 2012. The final sale price of $30.3 million includes the initial cash payment of $30.0 million and an additional cash payment related to a net working capital adjustment of $338,000. The proceeds were offset by $2.8 million in investment banking, legal and other fees related to the sale and $2.4 million in net balance sheet dispositions and write-offs.

In December 2011, we disposed of the extended warranty contracts related to the GDS Business, which were outstanding as of the date of the sale of the GDS Business but were not included in the August 2011 transaction. In exchange for transferring the liability related to the extended warranty contracts, which was previously recorded as deferred revenue, we made a cash payment to Devicor of $178,000. At the time of the transfer, we had current and deferred revenue reflected in our financial statements which was being amortized into income on a pro-rata basis over the life of the contracts. As a result of the transfer of obligations to Devicor, we recognized the unamortized deferred revenue of $1.2 million of non-cash income.

We recorded a net gain on the sale of the GDS business and disposal of the related extended warranty contracts of $26.2 million in 2011, which was reduced by estimated tax expense of $6.7 million during 2011.

As a result of our decision to hold Cardiosonix for sale, we reduced all assets and liabilities to their estimated fair value at that time, which resulted in an impairment loss of $1.1 million, primarily related to $1.3 million of intangible assets, $416,000 of inventory, and $30,000 of equipment, offset by $583,000 of related income tax benefit. The impairment loss was included in the loss from discontinued operations for the year ended December 31, 2009.

We estimate an allowance for doubtful accounts based on a review and assessment of specific accounts receivable and write off accounts when deemed uncollectible. The allowance for doubtful accounts at December 31, 2010 was $1,200. At December 31, 2010, approximately 87% of net accounts receivable were due from Devicor and EES. There were no accounts receivable related to discontinued operations at December 31, 2011.

During 2011, 2010 and 2009, we also wrote off $1,000, $65,000 and $2,000, respectively, of excess and obsolete gamma detection device materials.

Deferred revenue consists primarily of non-refundable license fees and reimbursement of past research and development expenses which EES paid us as consideration for extending our distribution agreement with them in prior years. During 2011, 2010 and 2009, we recognized license revenue of $63,000, $100,000, and $100,000, respectively. The unearned license revenue remaining at the date of the sale of the GDS Business was written off as part of the gain on the sale. In addition, deferred revenue includes revenues from the sale of extended warranties covering our medical devices over periods of one to five years. Prior to the disposal of the extended warranty contracts, we recognized revenue from extended warranty sales on a pro-rata basis over the period covered by the extended warranty.

Notes to the Consolidated Financial Statements

As a result of the sale of the GDS Business, we reclassified all related assets and liabilities as assets and liabilities associated with discontinued operations. We also reclassified all remaining assets and liabilities related to discontinued operations of our Cardiosonix subsidiary for all periods presented, the amounts of which are not significant. The following assets and liabilities have been segregated and included in assets associated with discontinued operations or liabilities associated with discontinued operations, as appropriate, in the consolidated balance sheets:

	December 31, 2011	December 31, 2010
Accounts receivable, net	$ 5,650	$ 1,917,213
Inventory, net	—	826,588
Other current assets	4,980	40,839
Assets associated with discontinued operations, current	10,630	2,784,640
Property and equipment, net of accumulated depreciation	—	114,248
Patents and trademarks, net of accumulated amortization	—	60,215
Assets associated with discontinued operations, non-current	—	174,463
Total assets associated with discontinued operations	$ 10,630	$ 2,959,103
Accounts payable	$ 5,400	$ 170,981
Accrued liabilities	4,664	279,167
Deferred revenue, current	—	654,430
Liabilities associated with discontinued operations, current	10,064	1,104,578
Deferred revenue, non-current	—	672,924
Liabilities associated with discontinued operations	$ 10,064	$ 1,777,502

Notes to the Consolidated Financial Statements

In addition, we reclassified revenues and expenses related to the GDS Business and our Cardiosonix subsidiary to discontinued operations for all periods presented. The following amounts, as well as the $26.2 million gain on the sale of the GDS Business and disposal of the related extended warranty contracts and the $1.7 million Cardiosonix impairment in 2009, have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

	Years Ended December 31,		
	2011	2010	2009
Net sales	$7,684,689	$10,140,476	$9,647,160
Cost of goods sold	2,324,427	3,230,575	3,185,584
Gross profit	5,360,262	6,909,901	6,461,576
Operating expenses:			
Research and development	564,194	371,794	635,863
Selling, general and administrative	308,220	258,452	418,111
Total operating expenses	872,414	630,246	1,053,974
Other expense, net	(1,084)	(529)	(800)
Income taxes	(1,157,230)	(2,134,903)	(1,838,312)
Income from discontinued operations	$3,329,534	$4,144,223	$3,568,490

Subsequent to the sale of the GDS Business, the Company re-evaluated its segment disclosures and determined that our radiopharmaceutical products under development constitute our only current line of business.

Notes to the Consolidated Financial Statements

3. Fair Value Hierarchy

The following tables set forth, by level, financial liabilities measured at fair value on a recurring basis:

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2011

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2011
Liabilities:				
Derivative liabilities related to warrants, current	$ —	$ 568,930	$ —	$ 568,930

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2010

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2010
Liabilities:				
Derivative liabilities related to warrants, current	$ —	$ 405,524	$ —	$ 405,524
Derivative liabilities related to warrants, long-term	—	2,077,799	—	2,077,799
Total derivative liabilities	$ —	$ 2,483,323	$ —	$ 2,483,323

There were no transfers in or out of our Level 1 and Level 2 fair value measurements during the years ended December 31, 2011 or 2010.

There were no Level 3 liabilities outstanding during the year ended December 31, 2011. The following table sets forth a summary of changes in the fair value of our Level 3 liabilities for the year ended December 31, 2010:

Year Ended December 31, 2010

Description	Balance at December 31, 2009	Unrealized Losses	Purchases, Issuances and Settlements	Transfers In and/or (Out)	Balance at December 31, 2010
Liabilities:					
Derivative liabilities related to put options	$ 966,000	$ —	$ (966,000)	$ —	$ —

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Notes to the Consolidated Financial Statements

4. Stock-Based Compensation

For the years ended December 31, 2011, 2010 and 2009, our total stock-based compensation expense was approximately $3.6 million, $598,000 and $445,000, respectively. We have not recorded any income tax benefit related to stock-based compensation for the years ended December 31, 2011, 2010 and 2009.

A summary of the status of our stock options as of December 31, 2011, and changes during the year then ended, is presented below:

	Year Ended December 31, 2011			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of year	5,734,500	$ 0.58		
Granted	281,000	3.56		
Exercised	(2,697,833)	0.35		
Forfeited	(2,667)	0.85		
Expired	—	—		
Outstanding at end of year	3,315,000	$ 1.02	4.1 years	$5,576,560
Exercisable at end of year	2,588,817	$ 0.67	2.8 years	$5,061,590

The weighted average grant-date fair value of options granted in 2011, 2010 and 2009 was $2.22, $1.13 and $0.68, respectively. During 2011, 2,697,833 stock options with an aggregate intrinsic value of $9,620,085 were exercised in exchange for issuance of 1,832,673 shares of our common stock, resulting in gross proceeds of $225,010. During 2010, 491,667 stock options with an aggregate intrinsic value of $697,662 were exercised in exchange for issuance of 350,156 shares of our common stock, resulting in gross proceeds of $32,550. During 2009, 465,000 stock options with an aggregate intrinsic value of $282,250 were exercised in exchange for issuance of 400,441 shares of our common stock, resulting in gross proceeds of $148,750. During 2011, 2010 and 2009, we paid tax withholdings related to stock options exercised of $2.8 million, $133,000, and $24,000, respectively. During 2011, 2010 and 2009, the aggregate fair value of stock options vested was $1.9 million, $668,000 and $343,000, respectively.

A summary of the status of our unvested restricted stock as of December 31, 2011, and changes during the year then ended, is presented below:

	Year Ended December 31, 2011	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of year	2,374,500	$ 1.07
Granted	922,000	3.49
Vested	(1,050,000)	1.27
Forfeited	(4,500)	0.65
Expired	(596,000)	0.80
Unvested at end of year	1,556,000	$ 2.48

During 2011 and 2009, 1,050,000 and 5,000 shares, respectively, of restricted stock vested with aggregate fair values of $4.2 million and $6,000, respectively. No restricted stock vested during 2010.

Notes to the Consolidated Financial Statements

As of December 31, 2011, there was approximately $1.5 million of total unrecognized compensation cost related to stock option and restricted stock awards, which we expect to recognize over remaining weighted average vesting terms of 2.1 years. See Note 1(e).

5. Earnings Per Share

Basic earnings (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares and, except for periods with a loss from operations, participating securities outstanding during the period. Diluted earnings (loss) per share reflects additional common shares that would have been outstanding if dilutive potential common shares had been issued. Potential common shares that may be issued by the Company include convertible securities, options and warrants.

The following table sets forth the reconciliation of the weighted average number of common shares outstanding to those used to compute basic and diluted earnings (loss) per share for the years ended December 31, 2010 and 2009:

	Basic and Diluted Earnings Per Share Years Ended December 31,		
	2011	2010	2009
Outstanding shares	95,398,961	86,319,913	80,936,711
Effect of weighting changes in outstanding shares	(3,333,635)	(3,218,915)	(5,445,840)
Unvested restricted stock	(1,556,000)	(2,374,500)	(1,719,000)
Adjusted shares	90,509,326	80,726,498	73,771,871

Earnings (loss) per common share for the years ended December 31, 2011, 2010 and 2009 excludes the effects of 55.7 million, 64.1 million and 58.8 million common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of common shares issuable upon exercise of outstanding stock options and warrants, and upon the conversion of convertible debt and convertible preferred stock.

The Company’s unvested stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as “participating securities”). Therefore, the unvested stock awards are included in the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, 1,556,000, 2,374,500 and 1,719,000 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the years ended December 31, 2011, 2010 and 2009, respectively,

because such inclusion would be anti-dilutive.

6. Inventory

The components of net inventory at December 31, 2011 and 2010 are as follows:

	2011	2010
Pharmaceutical materials	$482,000	$482,000
Pharmaceutical work-in-process	339,549	150,000
	$821,549	$632,000

During 2011 and 2010, we capitalized $213,000 and $741,000, respectively, of inventory costs associated with our Lymphoseek product. During 2010, we wrote off $634,000 of previously capitalized Lymphoseek inventory due to changes in our projections of the probability of future commercial use for the specific lots previously capitalized or the consumption of the Lymphoseek material in previously unanticipated product development activities.

Notes to the Consolidated Financial Statements

7. Property and Equipment

The major classes of property and equipment are as follows:

	Useful Life	2011	2010
Production machinery and equipment	5 years	$218,205	$218,205
Other machinery and equipment, primarily computers	3 – 5 years	399,587	426,778
Furniture and fixtures	7 years	416,005	423,769
Software	3 years	305,282	213,326
Leasehold improvements	Life of Lease[1]	102,150	84,027
		$1,441,229	$1,336,105

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

Property and equipment includes $20,000 and $40,000 of equipment under capital leases with accumulated amortization of $11,000 and $21,000 at December 31, 2011 and 2010, respectively. During 2011, 2010 and 2009, we recorded $117,000, $102,000 and $78,000, respectively, of depreciation and amortization related to property and equipment. We recorded net losses of $3,000 in 2011 and less than $1,000 in each of 2010 and 2009 on the disposal of property and equipment.

8. Accrued Liabilities and Other

Accrued liabilities and other at December 31, 2011 and 2010 consist of the following:

	2011	2010
Contracted services	$969,150	$602,704
Compensation	953,641	257,787
Capital lease obligations, current portion	5,572	8,620
Other	159,359	145,019
	$2,087,722	$1,014,130

9. Separation of David Bupp

In March 2011, Neoprobe announced the departure of our then-current President and CEO, David C. Bupp, effective April 15, 2011. The following table summarizes remaining accrued separation costs, including employer payroll tax obligations, related to the provisions of Mr. Bupp's separation agreement, which are included in accrued liabilities and other on the consolidated balance sheet as of December 31, 2011:

	As of December 31, 2011
Separation	$ 180,074
Pro-rated 2011 bonus	60,870
Estimated cost of continuing healthcare coverage	61,875
	$ 302,819

Concurrent with Mr. Bupp's separation, Dr. Mark J. Pykett was named Neoprobe's new President and CEO, effective April 15, 2011.

Notes to the Consolidated Financial Statements

10. Convertible Securities

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.

As a condition of the SPA, Montaur required 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, we agreed to provide security for the obligations evidenced by the amended Bupp Note (the Amended Bupp Note), under the terms of a Security Agreement, dated December 26, 2007, by and between the Company 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 achievement of a funding milestone set in the SPA, 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 achievement of a further funding milestone set in the SPA, 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 of the Series A Preferred Stock was $1,000 and the conversion price was set at $0.50, thereby making the shares of Series A Preferred Stock convertible into an aggregate 6,000,000 shares of our common stock, subject to certain adjustments 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.

Notes to the Consolidated Financial Statements

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 requirement 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, the Company 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 until December 31, 2011, 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, the Company recognized a loss on extinguishment of debt of $41.7 million, including the write-off of $966,000 in put option derivative liabilities, and recorded a deemed dividend of $8.0 million during the second quarter of 2010. As a result of these exchange transactions, all security interests in the Company’s assets held by Montaur and the Bupp Investors were extinguished.

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules), providing for loans to the Company in two advances totaling $10 million. Pursuant to the Loan Agreement, we issued Hercules: (1) a Secured Term Promissory Note in the principal amount of $7,000,000 (the First Advance), bearing interest at the greater of either (a) the U.S. Prime Rate as reported in The Wall Street Journal plus 6.75%, or (b) 10.0% (effective interest rate at December 31, 2011 was 10.0%), and (2) a Series GG Warrant to purchase 333,333 shares of our common stock at an exercise price of $2.10 per share, expiring in December 2016 (the Series GG Warrant). Additionally, pursuant to the terms of the Loan Agreement, if FDA approval of Lymphoseek occurs on or before June 30, 2012, Navidea has the option to draw a second advance in the principal amount of $3,000,000 (the Second Advance), bearing interest at the same rate and payable on the same terms as the First Advance. The Loan Agreement provides for an interest-only period beginning on December 29, 2011 and expiring on July 1, 2012, provided the interest-only period shall expire on January 1, 2013 upon Navidea’s receipt of FDA approval for Lymphoseek on or before June 30, 2012. The principal and interest is to be repaid in 30 equal monthly installments of principal and interest, payable on the first of each month following the expiration of the interest-only period. The outstanding balance of the debt is due December 1, 2014, or June 1, 2015 if the interest-only period is extended following FDA approval of Lymphoseek. Navidea has the option to pay up to $1.5 million of the principal amount of the debt in stock at a fixed conversion price of $2.77, subject to certain conditions. In addition, Hercules has the option to elect payment for up to another $1.5 million of the principal amount of the debt by conversion at a fixed conversion price of $2.77. The debt is collateralized by a security interest in substantially all of the Company’s assets except for intellectual property, as to which the security interest is in rights to income or proceeds from the sale or licensing thereof. The Loan Agreement also specifies certain covenants including the requirement that Navidea provide certain information, such as financial statements and budgets, on a periodic basis. As of December 31, 2011, we were in compliance with all such covenants.

In accordance with current accounting standards, Hercules' option to convert up to $1.5 million of the debt into stock was evaluated and determined to be a beneficial conversion feature. The beneficial conversion feature of $24,888 was recorded as a discount on the First Advance based on the market price of the Company's stock on the date of the Loan Agreement. In addition, the Series GG Warrant was accounted for as a liability at origination due to the existence of certain provisions in the instrument which will remain in effect for the first 365 days the warrant is outstanding. As a result, we recorded a current derivative liability with an estimated fair value of $520,478 on the date of issuance of the Series GG Warrant. The estimated fair value of the Series GG Warrant was recorded as a discount on the First Advance. Navidea paid or accrued total debt issuance costs of $593,339 including origination, legal, and other costs related to the loan. The total aggregate discounts on the First Advance of $545,366 and the debt issuance costs of $593,339 will be amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement.

Notes to the Consolidated Financial Statements

During the years ended December 31, 2011, 2010 and 2009, we recorded interest expense of $4,000, $16,000 and $428,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our convertible notes.

11. Derivative Instruments

Effective January 1, 2009, we adopted a new accounting standard which clarified the determination of whether equity-linked instruments (or embedded features), such as our convertible securities and warrants to purchase our common stock, are considered indexed to our own stock. As a result of adopting the new standard, certain embedded features of our convertible securities which were extinguished in the second quarter of 2010, as well as warrants to purchase our common stock, that were previously treated as equity were recorded as derivative liabilities. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.

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 as discussed in Note 10. As a result, the Company reclassified $27.0 million in derivative liabilities related to the Montaur Notes, the Series A Preferred Stock, and the Montaur Warrants to additional paid-in capital. Also in July 2009, Montaur exercised 2,844,319 of their Series Y warrants, which resulted in a decrease in the related derivative liability of $2.2 million. 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. As a result of this exchange transaction, the Company wrote off $966,000 in put option derivative liabilities during the second quarter of 2010.

In November 2010, we entered into agreements with certain institutional investors, pursuant to which the investors purchased $6.0 million of our common stock at $1.90 per share. In addition to the common stock, we issued two series of warrants to the investors: (1) 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 (2) two-year Series DD warrants to purchase 1,578,948 shares of our common stock at an exercise price of $2.11 per share. The Series CC and Series DD warrants originally contained language that required Navidea to classify the warrants as derivative liabilities, and we recorded them at their estimated fair values totaling $1.2 million. On December 23, 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 after marking the liabilities to market.

During 2010, 120,000 Series V warrants and 60,000 Series Z warrants were exercised. The Company reclassified $280,000 in derivative liabilities related to these warrants to additional paid-in capital.

In January 2011, certain Series V 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 the Series V warrants, we reclassified $1.4 million in derivative liabilities related to those warrants to additional paid-in capital during the first quarter of 2011. Also in January 2011, certain 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 the Series CC and Series DD warrants, we reclassified $549,000 in derivative liabilities related to those warrants to additional paid-in capital during the first quarter of 2011.

During 2011, Mr. Bupp and certain members of his family exercised 810,000 Series V warrants in exchange for issuance of 810,000 shares of our common stock, resulting in gross proceeds of $255,600. The net effect of marking the derivative liabilities related to the exercised Series V warrants to market resulted in net increases in the estimated fair values of the derivative liabilities of $119,000, which were recorded as non-cash expense. As a result of the Series V warrant exercises, we reclassified $96,000 in derivative liabilities related to those warrants to additional paid-in capital.

Notes to the Consolidated Financial Statements

Also during 2011, the holders of 60,000 Series Z warrants exercised them on a cashless basis in exchange for issuance of 46,902 shares of our common stock. The net effect of marking the derivative liabilities related to the exercised Series Z warrants to market resulted in net increases in the estimated fair values of the derivative liabilities of $79,000, which were recorded as non-cash expense. As a result of the Series Z warrant exercises, we reclassified $164,000 in derivative liabilities related to those warrants to additional paid-in capital.

In addition, the holders of Series CC warrants exercised them during 2011 in exchange for issuance of 1,578,948 shares of our common stock, resulting in gross proceeds of $3,331,580. Further, the holders of Series DD warrants exercised them during 2011 in exchange for issuance of 1,578,948 shares of our common stock, resulting in gross proceeds of $3,331,580. 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 $752,000, 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. See Note 12(b).

In December 2011, in connection with entering into the Loan Agreement with Hercules, we issued a Series GG Warrant to purchase 333,333 shares of our common stock at an exercise price of $2.10 per share, expiring in December 2016. The Series GG Warrant was accounted for as a liability at origination due to the existence of certain price reset provisions in the instrument which will remain in effect for the first 365 days the warrant is outstanding. As a result, we recorded a current derivative liability with an estimated fair value of $520,478 on the date of issuance of the Series GG Warrant. See Note 10.

Changes in the estimated fair values of our derivative liabilities are recorded in the consolidated statement of operations. The net effect of marking our derivative liabilities to market during the years ended December 31, 2011, 2010 and 2009 resulted in net increases in the estimated fair values of the derivative liabilities of $952,000, $1.3 million and $18.1 million, respectively, which were recorded as non-cash expense. The total estimated fair value of our derivative liabilities was $569,000 and $2.5 million as of December 31, 2011 and 2010, respectively.

12. Equity

a. **Common Stock Purchase Agreement:** In March 2010, we sold to Fusion Capital Fund II, LLC (Fusion Capital), an Illinois limited liability company, 540,541 shares for proceeds of $1.0 million under a common stock purchase agreement, as amended. In connection with this sale, we issued 120,000 shares of our common stock to Fusion Capital as an additional commitment fee. The agreement with Fusion Capital expired on March 1, 2011.

b. **Stock Warrants:** At December 31, 2011, there are 17.6 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from $0.31 to $2.375 per share with a weighted average exercise price per share of $0.56.

Notes to the Consolidated Financial Statements

The following table summarizes information about our outstanding warrants at December 31, 2011:

	Exercise Price	Number of Warrants	**Expiration Date**
Series V	$ 0.31	20,000	July 2012
Series W	0.32	6,000,000	December 2012
Series X	0.46	8,333,333	April 2013
Series AA	0.97	2,400,000	July 2014
Series BB	2.00	300,000	July 2015
Series EE	2.375	134,211	August 2015
Series FF	1.97	30,000	December 2015
Series GG	2.10	333,333	December 2016
	$ 0.56	17,550,877	

During 2009, David C. Bupp, our President and CEO, exercised 50,000 Series Q warrants in exchange for issuance of 50,000 shares of our common stock, resulting in gross proceeds of $25,000. The remaining 325,000 Series Q warrants held by Mr. Bupp expired during the year. During the same period, another Bupp Investor exercised 50,000 Series V warrants in exchange for issuance of 50,000 shares of our common stock, resulting in gross proceeds of $16,000. Also during 2009, certain outside investors exercised a total of 1,480,000 Series U warrants on a cashless basis in exchange for issuance of 848,507 shares of our common stock.

During 2010, a Bupp Investor exercised 120,000 Series V warrants in exchange for issuance of 120,000 shares of our common stock, resulting in gross proceeds of $37,200. Also during 2010, certain outside investors exercised a total of 60,000 Series Z warrants on a cashless basis in exchange for issuance of 37,778 shares of our common stock.

In July 2010, we issued five-year Series BB Warrants to purchase 300,000 shares of our common stock at an exercise price of $2.00 per share to an investment advisory firm in connection with a consulting agreement.

See Notes 10 and 11 for a discussion of Series GG warrant transactions during 2011. See Note 11 for a discussion of Series V, Series Z, Series CC, and Series DD warrant transactions during 2011.

c.

Common Stock Reserved: As of December 31, 2011, we have reserved 54,876,319 shares of authorized common stock for the exercise of all outstanding options, warrants, convertible preferred stock and convertible debt.

13. Income Taxes

As of December 31, 2011 and 2010, our deferred tax assets were approximately $37.7 million and $45.4 million, respectively. The components of our deferred tax assets are summarized as follows:

	As of December 31,	
	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	$29,701,483	$37,677,076
R&D credit carryforwards	7,610,672	6,006,233
Temporary differences	371,610	1,745,473
Deferred tax assets before valuation allowance	37,683,765	45,428,782
Valuation allowance	(37,683,765)	(45,428,782)
Net deferred tax assets	$—	$—

Notes to the Consolidated Financial Statements

Current accounting standards require a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. Due to the uncertainty surrounding the realization of these deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2011 and 2010.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income, and tax-planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences or tax carryforwards as of December 31, 2011.

As of December 31, 2011 and 2010, we had U.S. net operating loss carryforwards of approximately $74.1 million and $88.6 million, respectively. Of that amount, $9.1 million relates to stock-based compensation tax deductions in excess of book compensation expense (APIC NOLs) that will be credited to additional paid-in capital when such deductions reduce taxes payable as determined on a "with-and-without" basis. Accordingly, these APIC NOLs will reduce federal taxes payable if realized in future periods, but NOLs related to such benefits are not included in the table above.

At December 31, 2011 and 2010, we had U.S. R&D credit carryforwards of approximately $7.6 million and $6.0 million, respectively. U.S. net operating loss carryforwards of $16.6 million and $9.5 million and R&D credit carryforwards of $346,000 and $156,000 expired during 2011 and 2010, respectively. The details of our U.S. net operating loss and R&D credit carryforward amounts and expiration dates are summarized as follows:

	As of December 31, 2011	
Expiration	U.S. Net Operating Loss Carryforwards	U.S. R&D Credit Carryforwards
2012	$20,797,107	$ 1,064,623
2013	17,142,781	1,173,387
2014	—	130,359
2015	—	71,713
2016	—	39,128
2017	1,282,447	5,350

2018	337,714	2,905
2019	1,237,146	22,861
2020	3,246,062	218,332
2021	3,127,238	365,541
2022	2,863,443	342,898
2023	2,826,656	531,539
2024	13,753,769	596,843
2025	5,425,180	1,094,449
2026	2,083,722	1,950,744
Total carryforwards	$74,123,265	$ 7,610,672

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During the years ended December 31, 2011, 2010 and 2009, Cardiosonix recorded losses for financial reporting purposes of $19,000, $15,000 and $328,000, respectively. As of December 31, 2011 and 2010, Cardiosonix had tax loss carryforwards in Israel of approximately $7.6 million. Under current Israeli tax law, net operating loss carryforwards do not expire. Due to the uncertainty surrounding the realization of the related deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2011 and 2010.

Under Sections 382 and 383 of the IRC of 1986, as amended, the utilization of U.S. net operating loss and R&D tax credit carryforwards may be limited under the change in stock ownership rules of the IRC. During 2011, we analyzed past ownership changes as defined by Sections 382 and 383, which have occurred at various points in our history, and concluded that we are not currently subject to any Section 382 or 383 limitations. As such, we believe utilization of our net operating loss carryforwards and tax credit carryforwards will not be limited by changes in ownership.

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

	Years Ended December 31,					
	2011		2010		2009	
	Amount	%	Amount	%	Amount	%
Benefit at statutory rate	$(8,516,176)	(34.0)%	$(19,122,958)	(34.0)%	$(14,721,558)	(34.0)%
Adjustments to valuation allowance	—	—	3,410,056	6.1 %	7,816,084	18.1 %
Loss on extinguishment of debt	—	—	14,179,468	25.2 %	5,343,694	12.3 %
Permanent items and other	636,033	2.5 %	(601,469)	(1.1)%	306,167	0.7 %
Benefit per financial statements	$(7,880,143)		$(2,134,903)		$(1,255,613)	

14. Agreements

a. **Supply Agreements:** In November 2009, we entered into a manufacture and supply agreement with Reliable Biopharmaceutical Corporation (Reliable) for the manufacture and supply of the active pharmaceutical ingredient (API) of Lymphoseek. The initial ten-year term of the agreement expires in November 2019, with options to extend the agreement for successive three-year terms. Either party has the right to terminate the agreement upon mutual written agreement, or upon material breach by the other party which is not cured within 60 days from the date of written notice of the breach. Total purchases under the manufacture and supply agreement were $19,000 and $1.0 million for the years ended December 31, 2011 and 2010. As of December 31, 2011, we have issued purchase orders under the agreement with Reliable for $652,000 of our products for delivery through June 2012.

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

b. consideration for the license rights, we agreed to pay UCSD a license issue fee of $25,000 and license maintenance fees of $25,000 per year. We also agreed to pay UCSD milestone payments related to commencement of clinical trials and successful regulatory clearance for marketing of the licensed products, a 5% royalty on net sales of licensed products subject to a $25,000 minimum annual royalty, fifty percent of all sublicense fees and fifty percent of sublicense royalties. We also agreed to reimburse UCSD for all patent-related costs. Total costs related to the UCSD license agreement were $98,000, $36,000 and $63,000 in 2011, 2010 and 2009, respectively, and were recorded in research and development expenses.

Notes to the Consolidated Financial Statements

During April 2008, we completed a license agreement with UCSD for an expanded field of use allowing Lymphoseek to be developed as an optical or ultrasound agent. The license agreement is effective until the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD has granted us the exclusive rights to make, use, sell, offer for sale and import licensed products as defined in the agreement and to practice the defined licensed methods during the term of the agreement. We may also sublicense the patent rights, subject to certain sublicense terms as defined in the agreement. In consideration for the license rights, we agreed to pay UCSD a license issue fee of $25,000 and license maintenance fees of $25,000 per year. We also agreed to pay UCSD milestone payments related to commencement of clinical trials and successful regulatory clearance for marketing of the licensed products, a 5% royalty on net sales of licensed products subject to a $25,000 minimum annual royalty, fifty percent of all sublicense fees and fifty percent of sublicense royalties. We also agreed to reimburse UCSD for all patent-related costs. Total costs related to the UCSD license agreement were $28,000, $27,000 and $26,000 in 2011, 2010 and 2009, respectively, and were recorded in research and development expenses.

In December 2011, we executed a license agreement with AstraZeneca AB for AZD4694, a proprietary compound that is primarily intended for use in diagnosing Alzheimer's Disease and other central nervous system disorders. The license agreement is effective until the later of the tenth anniversary of the first commercial sale of AZD4694 or the expiration of the underlying patents. Under the terms of the license agreement, AstraZeneca granted us an exclusive worldwide royalty-bearing license for AZD4694 with the right to grant sublicenses. In consideration for the license rights, we paid AstraZeneca a license issue fee of $5.0 million upon execution of the agreement. We also agreed to pay AstraZeneca up to $6.5 million in contingent milestone payments based on the achievement of certain clinical development and regulatory filing milestones, and up to $11.0 million in contingent milestone payments due following receipt of certain regulatory approvals and the initiation of commercial sales of the licensed product. In addition, we agreed to pay AstraZeneca a royalty on net sales of licensed and sublicensed products. Total costs related to the AstraZeneca license agreement were $5.0 million in 2011, and were recorded in research and development expenses.

Cardiosonix's research and development efforts have been partially financed through grants from the Office of the Chief Scientist of the Israeli Ministry of Industry and Trade (the OCS). Through the end of 2004, Cardiosonix received a total of $775,000 in grants from the OCS. In return for the OCS's participation, Cardiosonix is committed to pay royalties to the Israeli Government at a rate of 3% to 5% of the sales of its products, if any, up to 300% of the total grants received, depending on the portion of manufacturing activity that takes place in Israel. In January 2006, the OCS consented to the transfer of manufacturing as long as we comply with the terms of the OCS statutes under Israeli law. We are not aware of any future performance obligations related to the grants received from the OCS. We do not believe we will be obligated to pay the OCS any amounts greater than any royalties due on future sales in the event that future sales are not sufficient to generate adequate revenue to completely cover the full amount of the grant. However, under certain limited circumstances, the OCS may withdraw its approval of a research program or amend the terms of its approval. Upon withdrawal of approval, Cardiosonix may be required to refund the grant, in whole or in part, with or without interest, as the OCS determines. Through December 2011, we have paid the OCS a total of $80,000 in royalties related to sales of products developed under this program. As of December 31, 2011, we have accrued obligations for royalties totaling less than $1,000.

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

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c. **Employment Agreements:** We maintain employment agreements with five of our officers. The employment agreements contain termination and/or change in control provisions that would entitle each of the officers to 1.5 to 2.5 times their annual salaries, vest outstanding restricted stock and options to purchase common stock, and continue certain benefits if there is a termination without cause or change in control of the Company (as defined) and their employment terminates. As of December 31, 2011, our maximum contingent liability under these agreements in such an event is approximately $2.4 million. The employment agreements also provide for severance, disability and death benefits.

15. Leases

We lease certain office equipment under a capital lease which expires in 2013. We also lease office space under an operating lease that expires in January 2013.

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

	Capital Leases	Operating Leases
2012	$6,900	$143,256
2013	5,750	8,930
	12,650	$152,186
Less amount representing interest	1,722	
Present value of net minimum lease payments	10,928	
Less current portion	5,572	
Capital lease obligations, excluding current portion	$5,356	

Total rental expense was $154,000, $125,000 and $115,000 for the years ended December 31, 2011, 2010 and 2009, respectively.

16. Employee Benefit Plan

We maintain an employee benefit plan under Section 401(k) of the Internal Revenue Code. The plan allows employees to make contributions and we may, but are not obligated to, match a portion of the employee's contribution with our common stock, up to a defined maximum. We also pay certain expenses related to maintaining the plan. We recorded expenses related to our 401(k) plan of $56,000, $37,000 and $29,000 during 2011, 2010 and 2009,

respectively.

17. Supplemental Disclosure for Statements of Cash Flows

During the years ended December 31, 2011, 2010 and 2009, we paid interest aggregating $4,000, $136,000 and $163,000, respectively. During the years ended December 31, 2010 and 2009, we issued 347,832 and 1,393,239 shares of our common stock, respectively, as payment of interest on our convertible debt and dividends on our convertible preferred stock. During 2011, 2010 and 2009, we issued 35,233, 53,499 and 80,883 shares of our common stock, respectively, as matching contributions to our 401(k) Plan. During the years ended December 31, 2011, 2010 and 2009, we transferred $25,000, $79,000 and $43,000, respectively, of GDS Business inventory to fixed assets related to the creation and maintenance of a pool of service loaner equipment. During 2010, we prepaid $71,000 in insurance through the issuance of notes payable to finance companies with a weighted average interest rate of 7.0%. During 2009, we purchased equipment under a capital lease totaling $20,000. During the year ended December 31, 2010, we reclassified $223,000 of deferred stock offering costs to additional paid-in capital related to the issuance of our common stock to Fusion Capital. See Note 12(a). Also during the year ended December 31, 2010, we recorded a deemed dividend of $8.0 million related to the exchange of the Series A Preferred Stock for Series B Preferred Stock. See Note 10.

Notes to the Consolidated Financial Statements

18. Contingencies

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

19. Subsequent Events

a. **Option Agreement:** In January 2012, Navidea entered into an option agreement with Alseres Pharmaceuticals, Inc. (Alseres) to license [^{123}I]-E-IAFCT Injection, also called Altropane®, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and movement disorders. The option agreement provides Navidea with exclusive rights for a period of up to six months to perform final due diligence and prepare the documentation necessary to enter into a definitive license agreement for [^{123}I]-E-IAFCT. Under the terms of the option agreement, we paid Alseres an option fee of $500,000 for the exclusive right to negotiate a definitive license agreement by June 30, 2012. Navidea may extend the option period through July 31, 2012 for an additional $250,000. The option agreement anticipates that Navidea will issue Alseres 400,000 shares of Navidea common stock upon execution of the definitive license agreement. The option also anticipates that the license agreement will provide for contingent milestone payments of up to $3.0 million, $2.75 million of which will principally occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.05 million shares of Navidea stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the license terms outlined in the option agreement anticipate royalties on net sales of the approved product which are consistent with industry-standard terms.

b. **Operating Lease:** In February 2012, Navidea entered into an operating lease agreement for approximately 3,800 square feet of office space in Andover, Massachusetts, just outside of Boston. The lease term will commence two weeks after completion of space renovation, which is currently expected in March 2012, and continue for 24 months at a monthly base rent of approximately $6,400. We must also pay a pro-rata portion of the utilities and real estate taxes of the building. The new office will house the Company's business development and commercialization team handling, in part, the activities surrounding the anticipated launch of Lymphoseek later this year. Navidea's corporate headquarters, including the clinical, manufacturing, regulatory and administration functions, remains in Dublin, Ohio.