NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-K
March 18, 2013

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, 2012

or

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

For the transition period from to _____ to _____

Commission file number H01-35076

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	31-1080091 (I.R.S. Employer Identification No.)
425 Metro Place North, Suite 450, Dublin, Ohio (Address of principal executive offices)	43017-1367 (Zip Code)

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

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

Common Stock, par value $.001 per share	NYSE MKT
(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.

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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, 2012 was $355,918,124.

The number of shares of common stock outstanding on March 1, 2013 was 117,610,966.

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. 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., a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. 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® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule, radiopharmaceutical designed for use in lymphatic mapping procedures that are performed to help stage certain solid tumors. Lymphoseek is intended to help identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek was approved for use in lymphatic mapping for breast cancer and melanoma by the U.S. Food and Drug Administration (FDA) on March 13, 2013. Additional trials, two of which are already ongoing in head and neck cancer and colorectal cancer, are anticipated to provide support for expanding the utilization of Lymphoseek into multiple other cancer types.
- NAV4694 is an F-18 radiolabeled positron emission tomography (PET) imaging agent being developed as an aid in the diagnosis of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD).

- NAV5001 is an Iodine-123 radiolabeled single photon emission computed tomography (SPECT) imaging agent being developed as an aid in the diagnosis of Parkinson's disease (PD) and other movement disorders, with potential additional use as a diagnostic aid in dementia.
- RIGScan™ is a radiolabeled monoclonal antibody being developed as a diagnostic aid for use during surgery to help surgeons locate occult or metastatic cancer, with a primary focus on colorectal cancer.

A Brief Look at Our History

We were originally incorporated in Ohio in 1983 and reincorporated in Delaware in 1988. From inception until January 2012, we operated under the name Neoprobe Corporation. In January 2012, we changed our name to Navidea Biopharmaceuticals, Inc. in connection with both the sale of our medical device business and our strategic repositioning as a precision diagnostics company focused on "NAVigating IDEAS" that result in the development and commercialization of precision diagnostic pharmaceuticals.

Since our inception, the majority of our efforts and resources have been devoted to the research and clinical development of radiopharmaceutical technologies primarily related to the intraoperative diagnosis and treatment of cancers. From the late 1990's through 2011, we devoted substantial effort towards the development and commercialization of medical devices, including a line of handheld gamma detection devices which was sold in 2011 and a line of blood flow measurement devices which we operated from 2001 through 2009.

From our inception through August 2011, we manufactured a line of gamma radiation detection medical devices called the neoprobe® GDS system (the GDS Business). From October 1999 through July 2010, the GDS products were marketed throughout most of the world 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 through a distribution arrangement with Devicor Medical Products, Inc. (Devicor), a successor to EES. During the fiscal years ended December 31, 2011 and 2010, we derived revenue from the sale of our GDS system products of $7.6 million and $10.0 million, respectively. Of those amounts, $7.4 million and $9.8 million, respectively, were derived from the sale of our GDS system products in the United States, and $166,000 and $182,000, 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 in May 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.

The cornerstone of our current business was established in 2001 when we restarted our pharmaceutical development by entering into a worldwide license agreement for Lymphoseek with the Regents of the University of California through their San Diego affiliate (UCSD). In 2004, we initiated our first corporate-sponsored clinical trial of Lymphoseek. Our business strategy is focused on advancing Navidea as a leader in the area of precision diagnostics, a field aimed at helping physicians deliver the right treatment to the right patient at the right time.

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 and Only FDA-Approved Receptor-Targeted Radiopharmaceutical Lymphatic Mapping Agent

Lymphoseek is a lymph node targeting radiopharmaceutical 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. Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA on March 13, 2013. Additional trials, two of which are already ongoing in head and neck cancer and colorectal cancer, are anticipated to provide support for expanding the utilization of Lymphoseek into multiple other cancer types.

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 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 ultimately revealed no sign of cancer, exposing patients to significant pain, morbidity, 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 nodes in this pathway – key predictive nodes called sentinel nodes that are most likely to harbor cancer – are 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. Regardless, a patient can be more accurately staged in light of knowledge that cancer has moved from the primary tumor site into the lymphatic system.

Lymphoseek: Tracing the Path to an ILM Advance

ILM has become the cancer-staging procedure of choice for oncology surgeons because it helps them focus on key predictive lymph nodes and reduce patient exposure to unnecessary surgical complications. Lymphoseek is a radiolabeled diagnostic for detection of the key predictive lymph nodes draining the tumor region. Lymphoseek is purposely-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 an approved comparator agent, vital blue dye (VBD). In Navidea's Phase 3 clinical studies of Lymphoseek, it detected over 97 percent of positive nodes identified by VBD. Conversely, VBD missed 31 percent of the overall nodes identified by Lymphoseek. More importantly, VBD missed 21 percent of nodes identified by Lymphoseek that were subsequently confirmed as containing cancer, whereas Lymphoseek missed less than 1 percent of these cancer-positive nodes, representing a greater than twenty-fold reduction in the rate at which cancer-positive lymph nodes were missed. Importantly, this resulted in 9.2% of subjects in our Phase 3 clinical studies being up-staged by the use of Lymphoseek in cases that would have been under-staged using VBD alone.

In the U.S., ILM employs a non-standard, Technetium 99mTc-labeled radiopharmaceutical agent known as sulfur-colloid (TcSC) which was recently approved by the FDA based on a literature review for use in ILM for breast cancer and melanoma. In contrast, Lymphoseek was studied in two well-controlled, prospective Phase 3 trials which compared Lymphoseek to VBD, the same color agent utilized in the literature-based FDA assessment of TcSC.

An abstract reviewing a meta-analysis of Phase 3 clinical trials for ILM of lymph nodes in breast cancer, compared to standard of care techniques including colloid agents, was published in conjunction with the 2012 Annual Meeting of the American Society of Clinical Oncology (ASCO). The abstract entitled, *"The novel receptor targeted (CD206) 99mTc-labeled tilmanocept versus the currently employed Tc99m-sulfur colloid in intraoperative lymphatic mapping (ILM) on key performance metrics in breast cancer"* was published in the *Journal of Clinical Oncology Online 2012; e21066*.

Assessment by meta-analysis and pooled analysis methods have been completed comparing Lymphoseek alone to TcSC plus VBD used together in subjects with breast cancer, employing the data provided in the FDA's approval of TcSC. Two endpoints were evaluated; the *Localization Rate,* which is the percentage of subjects with one or more radio-detected (Lymphoseek) or radio-detected and/or blue dye-positive (TcSC/VBD) nodes and the *Degree of Localization,* which is the number of nodes detected per subject. Both of these metrics help define the potential for an imaging agent's performance in ILM and the potential identification of metastasis to lymph nodes. The Localization

Rate for TcSC/VBD was 94%. The Localization Rate for Lymphoseek was statistically significantly greater at 99.91% by meta-analysis and 98.65% by pooled analysis ($p<0.0001$ and $p<0.008$, respectively). The Degree of Localization derived from the publication database for TcSC/VBD was 1.6 nodes per subject and for Lymphoseek it was 2.08 per subject by meta-analysis and 2.16 per subject by pooled analysis ($p<0.0001$ and $p<0.0001$, respectively). The analysis concluded that, in breast cancer, Lymphoseek provided significantly greater performance over the current ILM standard of care techniques in the key metrics of lymph node localization and identification of the number of lymph nodes found per subject.

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In June 2012, we published data developed from Phase 3 trials of Lymphoseek demonstrating important performance characteristics of Lymphoseek compared to a commercially available radiolabeled colloid used in intra-operative lymphatic mapping. The analysis evaluated the performance of Lymphoseek to a meta-analysis of published data for 99m-Tc-labeled nanocolloid human serum albumin (Nanocoll®), commercially available and considered a standard of care in Europe. Data for Nanocoll were derived from a meta-analysis of published literature that reported on the outcomes of localization rate (the proportion of subjects with at least one localized lymph node), and degree of localization (the average number of localized nodes relative to the subject population). Data for Lymphoseek were derived from a meta-analysis of two completed Lymphoseek Phase 3 clinical trials. Lymphoseek demonstrated a localization rate of 99.9% whereas Nanocoll showed a 95.9% localization rate. The degree of Lymphoseek localization was 2.16 (CI 1.99-2.36), whereas the colloid standard of care showed 1.67 (CI 0.94-0.98). The differences between Lymphoseek and Nanocoll in both of these parameters were statistically significant ($p < 0.0001$). The study, *"The efficacy of Tilmanocept in sentinel lymph node mapping and identification in breast cancer patients: a comparative review and meta-analysis of the 99m-Tc-labeled nanocolloid human serum albumin standard of care,"* can be found in the online edition of the peer-reviewed journal *Clinical and Experimental Metastasis [DOI 10.1007/s10585-012-9497-x]*. In September 2012, we announced the presentation of related data at the European Society of Surgical Oncology annual meeting.

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

- Improved presence in key predictive lymph nodes (distinct mechanism of action allows for effective identification of key tumor-draining lymph nodes)
- More rapid clearance of the injection site (detectable in lymph nodes within 10 minutes and up to 30 hours)
- Reduced patient trauma, morbidity and injection pain
- Faster nuclear medicine imaging – reduced nuclear medicine downtime (detectable in lymph nodes within 10 minutes and up to 30 hours)
- Enhanced operating room efficiency; reduced operating room idle time (ILM can be performed from 15 minutes up to 15 hours post-injection)
- 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 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 the 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. Additional non-clinical testing was successfully completed in late 2005. None of the non-clinical studies revealed any toxicity issues associated with the drug. To provide commercially-produced Lymphoseek needed for clinical study, Navidea engaged Reliable Biopharmaceutical Corporation (Reliable) to manufacture the drug substance and OSO BioPharmaceuticals Manufacturing LLC (OsoBio, formerly Cardinal Health PTS) for commercial manufacturing of the final drug product.

We completed a successful Phase 2 clinical study of Lymphoseek in 80 subjects in June 2007 and announced positive results later that year. 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 the FDA during late October 2007. Results of the study were published in the February 2011 online edition of the *Annals of Surgical Oncology*.

From 2008 to March 2009, we undertook and completed a Phase 3 clinical study in subjects with either breast cancer or melanoma (NEO3-05), 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 Phase 3 trial in subjects with head and neck squamous cell carcinoma on the head or in the mouth (NEO3-06). The NEO3-06 study was designed to expand the potential labeling for Lymphoseek to other cancer types and include a sentinel lymph node targeting claim.

In March 2010, Navidea met with the 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 the FDA for a pre-NDA assessment for Lymphoseek. As a result of the pre-NDA assessment, the 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.

Upon completion of the NEO3-09 study in early 2011, Navidea submitted the NDA for Lymphoseek in August 2011, and was notified of acceptance of the NDA by the 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 October 2012, we announced peer-reviewed publication of results of Lymphoseek from Phase 3 Clinical Trials in Melanoma in the *Annals of Surgical Oncology*. In the trials, a total of 154 subjects with melanoma from 15 centers received Lymphoseek followed by VBD and then underwent sentinel lymph node mapping. Lymph nodes that demonstrated Lymphoseek uptake and/or the presence of blue dye were removed and examined for the presence of tumor. Of the 235 blue-dyed lymph nodes removed from the 154 subjects, 232 (98.7%) demonstrated Lymphoseek uptake ($p<0.001$). The performance of Lymphoseek in intraoperative lymph node identification was also assessed. Of the 154 subjects injected with both Lymphoseek and VBD who underwent surgical removal of the lymph nodes, 150 subjects (97.4%) had at least one radioactive node due to Lymphoseek uptake, and 138 subjects (89.6%) had at least one blue node. This difference was statistically significant ($p<0.002$). Melanoma-containing lymph nodes were detected in 34 (22.1%) subjects; Lymphoseek identified all 45 melanoma-positive lymph nodes found in the 34 subjects. Four of these 34 node-positive subjects were detected exclusively by Lymphoseek. Blue dye detected 36 of the 45 melanoma-positive lymph nodes, but no melanoma-positive lymph nodes were detected exclusively by blue dye.

Clinical research continues with an ongoing Phase 3 trial involving subjects with head and neck squamous cell carcinoma (NEO3-06). The NEO3-06 clinical study was designed to provide evidence of Lymphoseek performance in a third cancer type and to potentially expand the product label for Lymphoseek. In January 2013, we announced that we had accrued sufficient subjects in our NEO3-06 study in subjects with head and neck cancer to enable us to conduct a pre-planned interim analysis. This Phase 3 trial of Lymphoseek is designed to demonstrate the performance of Lymphoseek in identifying sentinel lymph nodes in subjects with squamous cell carcinoma on the head or in the mouth. The interim analysis will compare the pathological analysis of the sentinel lymph nodes localized using Lymphoseek with that of all the lymph nodes removed during a full nodal dissection surgery of the head and neck. This full dissection surgery is considered the gold standard for determining the presence and extent of cancer and staging of the disease in such subjects. A total of 83 subjects who underwent pre-planned, full dissection surgery were enrolled to the interim analysis point. Results from three investigators participating in the NEO3-06 trial representing approximately half of the enrolled subjects were presented at major scientific conferences during 2012, all of which noted a 0% false negative rate in the subjects. Results from the full interim statistical analysis and reporting of the findings will be available upon completion of full site and data audits planned for later in 2013.

Following the FDA's acceptance of our Lymphoseek NDA filing in October 2011, the FDA established a Prescription Drug User Fee Act (PDUFA) date for Lymphoseek of June 10, 2012. In April 2012, the FDA notified us that the Agency had elected to modify the PDUFA date for Lymphoseek by 90 days to September 10, 2012 from the initial PDUFA date of June 10, 2012. On September 10, 2012, we received a complete response letter (CRL) from the FDA. The decision was focused on deficiencies in current Good Manufacturing Practices (cGMP) identified by the FDA during their pre-approval site inspections of third-party contract manufacturing facilities, and was not related to the efficacy or safety data filed within the Lymphoseek NDA. On October 30, 2012, we resubmitted our NDA in response to the CRL. Following the FDA's acceptance of our Lymphoseek NDA resubmission, the FDA established a new PDUFA date for Lymphoseek of April 30, 2013. Lymphoseek was subsequently approved and indicated for use in lymphatic mapping procedures in breast cancer and melanoma by the FDA on March 13, 2013.

Navidea was advised in February 2012 by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) that the Committee had adopted the advice of the Scientific Advice Working Party (SAWP)

regarding the Lymphoseek development program and 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. We submitted our MAA for Lymphoseek to the EMA in December 2012.

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

NAV4694 – Precision Imaging Agent to Aid in Diagnosis of Alzheimer's Disease

In December 2011, we executed a license agreement with AstraZeneca AB for NAV694, a proprietary compound that is primarily intended for use in diagnosing AD and other central nervous system disorders. The license agreement is effective until the later of the tenth anniversary of the first commercial sale of NAV4694 or the expiration of the underlying patents. Under the terms of the license agreement, AstraZeneca granted us an exclusive worldwide royalty-bearing license for NAV4694 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.

NAV4694 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. NAV4694 binds to beta-amyloid deposits in the brain that can then be imaged in 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, NAV4694 appears to have better sensitivity and specificity 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 low uptake in white matter background, better signal-to-noise ratios have been observed. Greater contrast may enable the ability to detect smaller amounts of amyloid and earlier identification of disease, as well as the opportunity to detect smaller changes in amyloid levels and monitor 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. Like PIB, these compounds are also high-resolution PET tracers, but utilize an F-18 isotope, which permits broader effective distribution.

These agents constitute a major step forward, but each has potential limitations. Navidea's NAV4694 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.

NAV4694 Clinical Development

NAV4694 has been studied in rigorous pre-clinical studies and several clinical trials in humans. Clinical studies through Phase 2 have included 140 subjects to date, both suspected AD patients and healthy volunteers. Results suggest that NAV4694 has the potential ability to image patients quickly and safely with high sensitivity and specificity. We are currently supporting a Phase 2 trial that we initiated in September 2012, primarily to expand the safety database for the compound. We also expect to initiate a Phase 2b trial in subjects with mild cognitive impairment in early 2013, as well as a Phase 3 autopsy-based trial in the first half of 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.

NAV5001

In January 2012, we executed an option agreement with Alseres Pharmaceuticals, Inc. (Alseres) to sublicense NAV5001. Under the terms of the option agreement, Navidea paid Alseres an option fee of $500,000 for the exclusive right to negotiate a definitive sublicense agreement by June 30, 2012. In order to perform thorough due diligence, Navidea extended the option period from June 30, 2012, to July 31, 2012. On July 31, 2012, we entered into an agreement to sublicense NAV5001 from Alseres. Under the terms of the sublicense agreement, Alseres granted Navidea an exclusive, worldwide sublicense to research, develop and commercialize NAV5001. The final terms of the agreement required Navidea to make a one-time sublicense execution payment to Alseres equal to (i) $175,000 in cash and (ii) 300,000 shares of our common stock. The sublicense agreement also provides for contingent milestone payments of up to $2.9 million, $2.5 million of which will principally occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.15 million shares of Navidea common stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the sublicense terms anticipate royalties on annual net sales of the approved product which are consistent with industry-standard terms and certain sublicense extension fees, payable in cash and shares of common stock, in the event certain diligence milestones are not met.

NAV5001 is a patented, novel, Iodine-123 labeled small molecule radiopharmaceutical used with SPECT imaging to identify the status of specific regions in the brains of patients suspected of having PD. 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 hallmark of PD.

NAV5001 has been administered to over 600 subjects to date. Results from clinical trials have demonstrated that NAV5001 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 PD and movement disorders, NAV5001 may also be useful in the diagnosis of Dementia with Lewy Bodies (DLB), one of the most common forms of dementia after AD. We expect to initiate a Phase 2b trial in subjects with DLB in the first half of 2013, as well as a Phase 3 trial in subjects with PD in the second half of 2013. 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.

RIGScan

RadioImmunoGuided Surgery (RIGS®) is a technique to provide diagnostic information during cancer surgery. RIGS is intended to enable a surgeon to identify and delineate occult or metastatic cancerous tissue "targeted" through the use of RIGScan, a radiolabeled, cancer-specific targeting antibody. RIGScan is administered prior to surgery and is identified by pre-operative imaging or during surgery with a gamma detection probe, thereby assisting a surgeon in identifying the location of cancerous tissues. 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 imaging methods prior to surgery or a gamma probe during surgery to direct the surgeon to targeted tissue for removal.

Our RIGScan technology is a radiolabeled murine monoclonal antibody that serves as the biologic targeting agent for intraoperative detection of occult or metastatic cancer. The antibody localizes or binds to tumor antigen called TAG-72 expressed on solid tumor cancers. 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 such cancers, potentially including colorectal cancer, ovarian cancer, prostate cancer and other cancers of epithelial origin. 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

The RIGScan approach 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 *Diseases of the Colon and Rectum*. In 1996, Navidea submitted applications to the EMA and the FDA for marketing approval of RIGScan for the detection of metastatic colorectal cancer based primarily on results of a single Phase 3 clinical trial, NEO2-14, but the FDA declined approval, indicating that, in addition to identifying additional pathology-confirmed disease, the clinical studies of RIGScan needed to demonstrate clinical utility in enhancing patient outcomes, an endpoint which the completed studies were not designed to address. Navidea withdrew its application to the EMA in November 1997.

To resume RIGScan development, we filed a new investigational new drug (IND) request with the FDA in late 2010. We held a pre-IND meeting with the FDA in February 2011 to define the basic chemistry, manufacturing and control (CMC) requirements needed to resume clinical development efforts on RIGScan. The 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. With this collective guidance, we have transitioned from a murine antibody to a humanized antibody. In September 2012, we were awarded a grant from the National Institutes of Health (NIH) to further the

development of RIGScan. The first phase of the grant, which has been awarded, is for $315,000; the second phase of the grant, which requires that we meet certain conditions, primarily investigational review board approval, will be for an additional $1.2 million. We have focused on manufacturing the humanized antibody with the aim of completing the necessary manufacturing steps to support the start of clinical development; however, as the scope and required resources for the RIGScan program, particularly in light of other development opportunities such as Lymphoseek, NAV4694, NAV5001, or other agents continues to be assessed, the timing and scope of our plans for RIGScan may be further affected.

RIGScan is a biologic drug that has not been produced for several years. We have completed the initial steps in assessing the materials required for future clinical testing. We will need to establish robust manufacturing and radiolabeling capabilities for the antibody in order to meet the regulatory needs for the RIGScan product. We cannot assure you that further clinical development will be successful, that the FDA or the EMA will clear RIGScan for marketing, or that it will be successfully introduced or achieve market acceptance. See Risk Factors.

Market Overviews

Cancer Market Overview

Cancer is the second leading cause of death in the U.S. and Western Europe. The American Cancer Society (ACS) estimates that cancer will cause over 580,000 deaths in 2013 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 that nearly 1.3 million new cases will occur in the U.S. in 2013. An analysis of Globocan 2008 estimates for these same cancer types indicates an annual incidence rate for these cancer types in excess of 7.2 million cases outside the U.S.

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 probability of developing breast cancer generally increases with age, rising from about 0.5% in women under age 40 to 6.7% in women age 70 or older. 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 232,000 new cases of invasive breast cancer are expected to be diagnosed during 2013 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. 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.

The use of ILM is also common in melanoma. The ACS estimates that approximately 77,000 new cases of melanoma will be diagnosed in the U.S. during 2013. In addition to breast cancer and melanoma, we believe that our oncology products may have utility in other cancer types with another 1 million new cases expected during 2013 in the U.S.

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 other solid tumor cancers such as prostate, gastric, colon, head and neck, and non-small cell lung.. However, we cannot assure you that Lymphoseek will be cleared to market for cancers other than breast or melanoma, or if cleared to market for other cancer types, 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 2012. On a global basis, Alzheimer's Disease International estimated in 2010 that there were 36 million people living with dementia. AA estimates that total costs for AD care will be approximately $200 billion in 2012. AA also estimates that there are over 15 million AD and dementia caregivers providing 17.4 billion hours of unpaid care valued at over $210 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. In February 2013, the American Academy of Neurology reported in the online issue of *Neurology* that the number of people with AD may triple by 2050.

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 five years could reduce the disease prevalence by 50% during the next few decades and, according to estimates from AA, reduce annual healthcare expenditures by more than $50 billion.

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.

Parkinson’s Disease Market Overview

Parkinson’s disease, following AD, is the second-most common neurodegenerative disorder in the United States. The Parkinson’s Disease Foundation (PDF) estimates that up to 10 million people worldwide are living with PD, including 1 million people in the U.S. Approximately 60,000 new cases of PD are diagnosed in the U.S. each year. The Centers for Disease Control rated complications from PD as the 14th leading cause of death in the U.S. and as with AD, there is no cure.

A recent article conservatively estimates that the combined direct and indirect cost of PD exceeds $14.4 billion per year. There are approved therapies for the treatment of PD symptoms but these treatments often become ineffectual as the disease progresses and none have been approved to modify, slow or reverse the disease progression. The burden of this chronic condition is projected to grow substantially over the next few decades as the size of the elderly population grows. Such projections are driving the need for innovative new treatments to prevent, delay onset, or alleviate symptoms of PD. Slowing Parkinson's progression by 50% would reduce health care costs for PD patients by 35%, representing a dramatic reduction in cost of care even when spread over a longer expected survival and positively impacting the patient quality of life.

PD is commonly misdiagnosed or completely missed in clinical evaluations as symptoms are often attributed to the normal aging process. Essential tremor and other similar conditions including DLB, AD, multiple system atrophy, progressive supranuclear palsy, and normal pressure hydrocephalus are also common sources of confusion in PD diagnosis. Collectively, there are over 25 million people in the U.S. and Europe with some type of movement disorder, comprising a large differential diagnosis population. Current diagnostic guidelines are limited since they characterize PD by the presence of motor symptoms. Error rates using clinical diagnostic methods have been reported to be high. Research has shown the importance of who is undertaking a potential PD diagnosis by showing data that nearly half (47%) of PD diagnoses are incorrect when performed in the primary care setting, and specialists whose expertise is not specific movement disorders have an error rate of approximately 25%, while movement disorder specialists are

mistaken in only 6% to 8% of cases.

The interest by the medical community in using imaging as an aid in diagnosing neurological conditions is growing. In PD, people lose dopamine-producing cells in a part of the brain associated with movement. Loss of these cells is the hallmark of PD. Current neuroimaging agents in combination with SPECT imaging are able to aid physicians in their diagnosis by visualizing this area of the brain to show the degree of loss of these motor neurons.

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/Mallinckrodt GE Healthcare, IBA Molecular, Advanced Accelerator Applications, Eckert & Zeigler AG, Lantheus Medical Imaging and Bracco Imaging.

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 FDA marketing clearance, March 13, 2013. 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 NAV4694, NAV5001 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 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 they are expected to be used in the ongoing Phase 3 clinical work. Reliable has produced the drug substance and OsoBio 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 will be made radioactive (radiolabeled) with technetium-99m (^{99m}Tc) to become the final form of Lymphoseek to be administered to a patient. The commercial manufacturing processes at Reliable and OsoBio are being concurrently validated in parallel with the approval and commercial launch of Lymphoseek. Both organizations have assisted Navidea in the preparation of the CMC sections of our submissions to the FDA and the EMA. Both Reliable and

OsoBio are registered manufacturers with the FDA and/or the EMA.

In November 2009, we completed a Manufacture and Supply Agreement with Reliable for the manufacture of the bulk drug substance with an initial term of 10 years. At this point, drug product produced by OsoBio has been manufactured under clinical development agreements. A commercial supply agreement with OsoBio is in process. We cannot assure you that we will be successful in reaching a commercial supply agreement with OsoBio on terms satisfactory to us, or at all.

NAV4694 Manufacturing

Supplies of NAV4694 used in clinical development through Phase 2b were manufactured by AstraZeneca through various arrangements. As a part of the technology transfer process related to our license of NAV4694, we are in the process of identifying and contracting with third party manufacturers and radiolabeling contractors necessary to build an integrated supply chain to produce the drug product for use in further clinical studies as well as for subsequent commercial use. We are producing drug substance, and are developing a commercial drug product kit, along with a commercial radiolabeling process and building a network of partners for the manufacture and distribution of NAV4694. We cannot assure you that we will be successful in executing agreements for the supply of NAV4694 on terms acceptable to the Company, or at all.

NAV5001 Manufacturing

Supplies of NAV5001 used in clinical development through Phase 3 were manufactured by Alseres under an agreement they had in place with Nordion, Inc. (Nordion), a Canadian corporation and well-recognized manufacturer of ^{123}I and nuclear medicine labeled imaging agents. As a part of the technology transfer process related to our sublicense of NAV5001, we have begun the process of identifying potential manufacturers and have initiated preliminary negotiations to produce the drug product for use in further clinical studies as well as for subsequent commercial use. We cannot assure you that we will be successful in completing a supply agreement on terms acceptable to the Company, or at all.

RIGScan Manufacturing

During the third quarter of 2009, we announced that we had executed a Biopharmaceutical Development and Supply Agreement for RIGScan with Laureate Biopharmaceutical Services, Inc. We will need to re-establish radiolabeling capabilities for the antibody in order to meet the regulatory needs for the RIGScan product. We cannot assure you that we will be successful in completing the necessary development or supply agreements to support RIGScan development or commercialization on terms acceptable to the Company, or at all.

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, including compliance with FDA cGMP requirements. 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.

Lymphoseek Competition

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 the 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. The product label for sulfur colloid was expanded to cover lymphatic mapping in melanoma in August 2012, again on the basis of a meta-analysis of published literature. In the EU 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”.

NAV4694 Competition

Several potential competitive ^{18}F products have been approved or are in development for use as biomarkers to aid in detection of AD. Developed through Eli Lilly’s wholly-owned Avid Radiopharmaceuticals (Avid), florbetapir was reviewed in January 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. In March 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. In April 2012, Avid received FDA approval to market florbetapir. Florbetapir also received marketing authorization in the EU in January 2013.

In addition to fluorbetipir, there are two other beta-amyloid imaging agents in late stage development: florbetaben from Piramal Enterprises, Imaging Division, who acquired a molecular imaging research and development portfolio from Bayer Pharma AG in April 2012, and flutemetamol from GE Healthcare. Both have completed Phase 3 trials. Data from the Phase 3 study of florbetaben was presented in April 2012. The study was designed to evaluate the power of florbetaben to identify whether a suspected AD patient has cerebral beta-amyloid deposits. The data were verified by histological verification in a postmortem autopsy. GE Healthcare is developing another PIB derivative, flutemetamol, for similar application. NDA and MAA submissions for flutemetamol have been accepted by the FDA and EMA, respectively. The NDA and MAA submissions were based on data from a series of clinical trials, including Phase 3 brain autopsy and biopsy studies which showed high sensitivity and specificity for visual image reads as well as strong concordance between [^{18}F]flutemetamol PET images and beta amyloid brain pathology. Data from these studies were presented at the Alzheimer's Association International Conference 2012 in Vancouver and the American Academy of Neurology's 64th Annual Meeting in New Orleans. The filing also includes data from a recently completed [^{18}F]flutemetamol PET image reader training validation study, results of which will be presented at a scientific forum in coming months.

NAV5001 Competition

In July 2000,GE Healthcare received EMA approval to market DaTscan™(Ioflupane ^{123}I Injection), a radiopharmaceutical agent intended for use with SPECT imaging for the detection of dopamine transporters in the brains of adult patients with suspected Parkinsonian syndromes, in the EU. DaTscan was developed to help physicians evaluate neurodegenerative movement disorders, such as idiopathic (of unknown cause) PD. In July 2006, GE Healthcare received expanded approval for DaTscan for use in DLB. For patients with dementia, DaTscan has been successfully used in Europe to separate Alzheimer's disease from DLB. This has important implications in determining which medications can be safely used to treat the dementia. GE Healthcare received FDA approval to market DaTscan in the U.S. in January 2011.

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. We also employ a variety of security measures to preserve the confidentiality of our trade secrets and to limit access by unauthorized persons. We cannot assure you, however, that these measures will be adequate to protect our trade secrets from unauthorized access or disclosure.

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.

NAV4694 Intellectual Property

NAV4694 is being developed under exclusive worldwide license from AstraZeneca. The NAV4694 license grants Navidea commercialization rights to the F-18 labeled biomarker for use as an aid in the diagnosis of AD. NAV4694 is the subject of 2 issued patents and 1 patent pending in the U.S. and 9 issued patents and 57 patents pending in 31 foreign jurisdictions. In addition, the [^{18}F]NAV4694 drug substance and NAV4694 Precursor 214 are the subjects of 2 issued patents and 1 patent pending in the U.S. and 9 issued patents and 57 patents pending in 31 foreign jurisdictions.

NAV5001 Intellectual Property

NAV5001 is being developed under an exclusive sublicense from Alseres. The NAV5001 sublicense grants Navidea commercialization rights to the Iodine-123 labeled biomarker for use as an aid in the diagnosis of PD and other movement disorders, with potential use as a diagnostic aid in dementia. NAV5001 is the subject of 3 issued patents and 1 patent pending in the U.S., 1 issued patent in Europe, and 9 patents pending in 3 foreign jurisdictions.

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 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, the 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, the FDA and the corresponding state, local and foreign regulatory bodies in jurisdictions in which our products are intended to be 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, the FDA and certain foreign regulatory bodies have pursued a more rigorous enforcement program to ensure that regulated businesses like ours comply with applicable laws and regulations. We devote significant time, effort and expense addressing the extensive governmental regulatory requirements applicable to our business. To date, we have not received a noncompliance notification or warning letter from the FDA or any other regulatory bodies of alleged deficiencies in our compliance with the relevant requirements, nor have we recalled or issued safety alerts on any of our products. However, we cannot assure you that a warning letter, recall or safety alert, if it occurred, would not have a material adverse effect on our company. See Risk Factors.

In the early- to mid-1990s, the review time by the FDA to clear medical products for commercial release lengthened and the number of marketing clearances decreased. In response to public and congressional concern, the FDA Modernization Act of 1997 (the 1997 Act) was adopted with the intent of bringing better definition to the clearance process for new medical products. While the FDA review times have improved since passage of the 1997 Act, we cannot assure you that the 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 the 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 the 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 the 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, the 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 the 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 the 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 subject 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 subject 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 the 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.

The 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 (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 the 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 the FDA. Before approving a NDA, the 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 the FDA evaluates the NDA

and the manufacturing facilities as acceptable, the FDA may issue an approval letter or a complete response letter. A complete response letter outlines conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of approval, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy, or impose other post-approval commitment conditions.

The NDA for Lymphoseek was submitted with the intention for use in intraoperative lymphatic mapping across a broad range of cancers. As a part of their review, the FDA examined the pre-clinical, clinical and CMC data supporting our application, and, as is also typical of such reviews, conducted 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. On September 10, 2012, we received a CRL from the FDA, denying our initial application for approval of Lymphoseek. The decision was focused on deficiencies in cGMP identified by the FDA during their pre-approval site inspections of third-party contract manufacturing facilities, and was not related to the efficacy or safety data filed within the Lymphoseek NDA. We worked diligently with our advisors, contract manufacturers and the FDA to address the third party cGMP manufacturing deficiencies noted in the FDA's September CRL. On October 30, 2012, we resubmitted our NDA in response to the CRL. The FDA accepted the resubmission and established a new PDUFA date of April 30, 2013. Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA on March 13, 2013. Additional trials, two of which are already ongoing in head and neck cancer and colorectal cancer, are anticipated to provide support for expanding the utilization of Lymphoseek into multiple other cancer types. We cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any market outside the U.S., or if approved, that it will achieve market acceptance in any market. See Risk Factors.

The FDA has various programs, including fast track, priority review and accelerated approval, which are intended to expedite or simplify the process of 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 assure you 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.

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.

Post-Approval Requirements

Holders of an approved NDA are required to: (i) conduct pharmacovigilance and report certain adverse reactions to the 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. The 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 U.S., 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 member 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. We cannot assure you 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 from the FDA and from 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 licenses 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. The 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.

Financial Statements

Our consolidated financial statements and the related notes, including revenues, income (loss), total assets and other financial measures are set forth at pages F-1 through F-26 of this Form 10-K.

Research and Development

We spent approximately $16.9 million, $15.2 million and $8.9 million on research and development activities in the years ended December 31, 2012, 2011 and 2010, respectively.

Employees

As of March 1, 2013, we had 47 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.

If we do not achieve commercial success with our approved product or 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 the neoprobe GDS line of gamma detection medical devices in August 2011. Through that time, sales of gamma detection devices represented our primary source of revenue. As a result, our near-term financial success depends in large part on Lymphoseek achieving commercial success in the U.S. and, pending approval in other markets, on achievement of commercial success in those markets as well. Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA on March 13, 2013. Additional trials, two of which are already ongoing in head and neck cancer and colorectal cancer, are anticipated to provide support for expanding the utilization of Lymphoseek into multiple other cancer types. We expect to begin generating revenues from product sales of Lymphoseek in the second quarter of 2013. As we generate revenues from Lymphoseek, it is possible we will ultimately receive payments related to the achievement of certain sales milestones by our marketing partner in the U.S. However, we cannot assure you that Lymphoseek will achieve commercial success in the U.S. or any other global market, that we will realize sales at levels necessary for us to achieve sales milestone payments, or that revenue from Lymphoseek will lead to us becoming profitable.

In addition, NAV4694, NAV5001 and RIGScan are in various stages of clinical development. Regulatory approval for additional indications for Lymphoseek may not be successful, or if successful, may not result in increased sales. Additional clinical trials for NAV4694, NAV5001, 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 which will provide sufficient revenue to make us profitable.

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
- upon being developed, they are approved by the regulatory authorities.

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

We cannot guarantee that we will obtain regulatory approval to manufacture or market our unapproved drug candidates and our approval to market our products or anticipated commercial launch 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, adverse medical events during a clinical trial, or issues related to CMC processes could also delay, limit or prevent regulatory approval. 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.

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

Approved products may later cause adverse effects that limit or prevent their 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 in 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 the 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. With the exception of Lymphoseek, now approved for use in lymphatic mapping in breast cancer and melanoma in the U.S., 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 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 to in-license 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 third parties, consisting of Lymphoseek, NAV4694, NAV5001 and RIGScan. We may not successfully acquire additional 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. These Phase 3 clinical trials served as the basis for the approval of Lymphoseek in March 2013.

Clinical research of Lymphoseek continues with an ongoing third Phase 3 trial involving subjects with head and neck squamous cell carcinoma (NEO3-06). The NEO3-06 clinical study was designed to provide evidence of Lymphoseek performance in a third cancer type and to potentially expand the product label for Lymphoseek. In January 2013, we announced that we had accrued sufficient subjects in our NEO3-06 study in patients with head and neck cancer to enable us to conduct a pre-planned interim analysis. This Phase 3 trial of Lymphoseek was designed to demonstrate the performance of Lymphoseek in identifying sentinel lymph nodes in subjects with squamous cell carcinoma on the head or in the mouth. The interim analysis will compare the pathological analysis of the sentinel lymph nodes localized using Lymphoseek with that of all the lymph nodes removed during a full nodal dissection surgery of the head and neck. This full dissection surgery is considered the gold standard for determining the presence and extent of cancer and staging of the disease in such patients. A total of 83 subjects who underwent pre-planned, full dissection surgery were enrolled and represent the interim analysis cohort. Results from the interim statistical analysis and reporting of the findings are expected to be available upon completion of full site and data audits planned for later in 2013.

With respect to NAV4694, AstraZeneca has completed clinical development through a Phase 2a level. During the third quarter of 2012, we commenced our clinical development through some additional Phase 2 testing, mainly intended to expand the safety population, and we intend to commence Phase 2b testing in patients with mild cognitive impairment and autopsy-based Phase 3 testing of NAV4694 in 2013, but these plans could also experience complications and delays.

With respect to NAV5001, Alseres had previously completed five clinical trials in over 600 subjects. Alseres received a Phase 3 SPA from the FDA for NAV5001 in 2009. We have held preliminary discussions with the FDA regarding the SPA and expect to update the SPA over the coming months.

In August 2011, we held a meeting regarding RIGScan with the SAWP of the EMA and received similar guidance as we received from the 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 our development plans from a murine-based antibody to a humanized antibody on our development and regulatory timelines. As the scope and required resources for other

development opportunities such as for NAV4694 and/or NAV5001 continues to be assessed, the timing and scope of our development and commercialization plan for RIGScan may be continue to be affected.

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, the FDA or the 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 clinical trials for Lymphoseek as indicated by the recent FDA approval, and our licensing partners have also achieved successful outcomes from earlier trials of NAV4694 and NAV5001, the results of some of these clinical trials that have not been yet reviewed by the FDA or other regulatory bodies, 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.

We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We rely on independent third-party contract research organizations (CROs) to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, post-study audits and statistical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely impacted.

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 or regulatory compliance issues 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 (CMS) in the months following FDA approval on March 13, 2013, there can be no assurance that such pass-through code will be received from CMS, 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 are in the process of establishing commercial manufacturing capabilities on a third-party contract basis for our Lymphoseek product and clinical manufacturing capabilities for our other radiopharmaceutical compounds. 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 to manufacture the drug substance for our Lymphoseek product and we currently use OsoBio 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, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products, and for approved products, any such delays, interruptions or other difficulties may render us unable to supply sufficient quantities to meet demand. Any such delays or interruptions may lower our revenues and potential profitability.

We and any third-party manufacturers that we may use must continually adhere to cGMPs and regulations enforced by the 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, the 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.

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. Physicians may use our competitors' products and/or our products may not be competitive with other technologies. Lymphoseek is expected to compete against sulfur colloid in the U.S. and other colloidal agents in other global markets. NAV4694 is expected to compete against florbetapir, a first-generation beta-amyloid imaging agent which Eli Lilly received approval for in 2012. We are also aware of two additional first-generation beta-amyloid imaging agents in late stages of development by two other large pharmaceutical companies. In addition, NAV5001 if approved, is expected to compete against a product marketed by GE Healthcare. If our competitors are successful in establishing and maintaining market share for their products, our sales and revenues may not occur at the rate we anticipate. 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.

We may be exposed to product liability claims for our product candidates and products that we are able to commercialize.

The testing, manufacturing, marketing and use of our commercial products, as well as product candidates in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. In recent years, coverage and availability of cost-effective product liability insurance has decreased, so we may be unable to maintain sufficient coverage for product liabilities that may arise. In addition, the cost to defend lawsuits or pay damages for product liability claims may exceed our coverage. If we are unable to maintain adequate coverage or if claims exceed our coverage, our financial condition and our ability to clinically test our product candidates and market our products will be adversely impacted. In addition, negative publicity associated with any claims, regardless of their merit, may decrease the future demand for our products and impair our financial condition.

The administration of drugs in humans, whether in clinical studies or commercially, carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our products or product candidates may cause, or may appear to have caused, injury or dangerous drug interactions, and we may not learn about or understand those effects until the product or product candidate has been administered to patients for a prolonged period of time. We may be subject from time to time to lawsuits based on product liability and related claims, and we cannot predict the eventual outcome of any future litigation. We may not be successful in defending ourselves in the litigation and, as a result, our business could be materially harmed. These lawsuits may result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business if in excess of our insurance coverage. Additionally, lawsuits can be expensive to defend, whether or not they have merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in managing our business.

As a result of a number of factors, product liability insurance has become less available while the cost has increased significantly. We currently carry product liability insurance that our management believes is appropriate given the risks that we face. We will continually assess the cost and availability of insurance; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

If any of our license agreements for intellectual property underlying Lymphoseek, NAV4694, NAV5001 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, NAV4694, NAV5001 and RIGScan. We may also 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 their agreements 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, most patent applications are secret for a period of 18 months after filing, and in foreign countries, patent applications are secret for varying periods of 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.

Under recent changes to U.S. patent law, the U.S. has moved to a “first to file” system of patent approval, as opposed to the former “first to invent” system. As a consequence, delays in filing patent applications for new product candidates or discoveries could result in the loss of patentability if there is an intervening patent application with similar claims filed by a third party, even if we or our collaborators were the first to invent.

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 unauthorized 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 and Alseres, 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, NAV4694, NAV5001 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. We also have limited rights to enforce patents and patent applications licensed from AstraZeneca and Alseres. 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, Alseres, the 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 our 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.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, and personally identifiable information of employees and clinical trial subjects, in our data centers and on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations, and damage our reputation, which could adversely affect our business, revenues and competitive position.

Failure to comply with domestic and international privacy and security laws can result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws, including protecting electronically stored information from cyber attacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to The Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

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 resources, and to acquire new product candidates. In order to support the initiatives envisioned in our business plan, we will 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 Lymphoseek does not generate our expected levels of sales and cash flow. 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 MKT 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 MKT 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 MKT. The NYSE MKT 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 MKT exchange could result in the delisting of our common stock." If our common stock were delisted from the NYSE MKT, 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 MKT'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 MKT 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 MKT staff. Based on our outstanding common stock as of February 28, 2013 and the average closing price of $3.11 over the thirty trading days preceding February 28, 2013, we could not raise more than approximately $70 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 MKT 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 MKT 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 MKT rules typically involves broadly announcing the proposed transaction, which often 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 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 with Hercules Technology II, LP (Hercules).

In addition to the security interest in our assets, the Loan and Security 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 outstanding balance of 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 and Security Agreement;
- we provide certain financial information and reports to Hercules in a timely manner; and
- we indemnify Hercules against certain liabilities.

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Additionally, with certain exceptions, the Loan and Security 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 or without prior written approval;
- 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 and Security 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.

Due to the extension of the PDUFA date for Lymphoseek to September 10, 2012, we did not receive FDA approval of Lymphoseek by the June 30, 2012 deadline established in the Loan and Security Agreement with Hercules, and therefore expect that additional loan proceeds of up to $3 million thereunder will not be available to us under the current terms.

In addition, our Loan Agreement with Platinum-Montaur Life Sciences, LLC (Montaur) carries covenants typical for commercial loan agreements, and similar to those contained in the Hercules Loan and Security Agreement, that impose significant requirements on us. 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 Montaur to terminate our ability to obtain additional draws under the Loan Agreement and accelerate the maturity of the debt. Such actions by Montaur 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 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 indebtedness and preferred stock restrict payment of dividends on our common stock, and future indebtedness and preferred stock may restrict payments 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 and continuing federal budget deadlock 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. The continuing federal budget deadlock not only may adversely affect financial markets, but could also delay or reduce research grant funding and adversely affect operations of government agencies that regulate us, including the FDA, potentially causing delays in obtaining key regulatory approvals.

Our failure to maintain continued compliance with the listing requirements of the NYSE MKT exchange could result in the delisting of our common stock.

Our common stock has been listed on the NYSE MKT since February 2011. The rules of NYSE MKT 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 MKT 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 MKT may consider suspending trading in, or removing the listing of, 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. As of December 31, 2012, the Company had a stockholders' deficit of approximately $1.4 million. However, the NYSE MKT will not normally consider removing from the list securities of an issuer that fails to meet these requirements if the issuer has (1) total value of market capitalization of at least $50,000,000; or total assets and revenue of $50,000,000 each in its last fiscal year, or in two of its last three fiscal years; and (2) the issuer has at least 1,100,000 shares publicly held, a market value of publicly held shares of at least $15,000,000 and 400 round lot shareholders. Based on the number of outstanding shares of our common stock, recent trading price of that stock, and number of round lot holders, we believe that we meet these exception criteria and that our common stock will not be delisted as a result of our failure to meet the minimum stockholders' equity requirement for continued listing. We cannot assure you that the Company will continue to meet these and other requirements necessary to maintain the listing of our common stock on the NYSE MKT. 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 MKT continued listing standards.

The delisting of our common stock from the NYSE MKT 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 $2.14 per share and as high as $4.77 per share during the 12-month period ended February 28, 2013. 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 MKT on February 10, 2011, trading in our common stock has been more active. During the 12-month period beginning on March 1, 2012 and ending on February 28, 2013, the average daily trading volume for our common stock on the NYSE MKT was approximately 850,000 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 MKT 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 MKT. 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. While we periodically are engaged in discussions regarding potential business or product acquisitions, we currently have no binding 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 expires October 31, 2013, at a monthly base rent of approximately $12,000 during 2013. We must also pay a pro-rata portion of the operating expenses and real estate taxes of the building. We also lease approximately 4,000 square feet of office space at 10 New England Business Center Drive, Andover, Massachusetts, primarily for our business development and commercialization departments. The current lease term expires March 2014, at a monthly base rent of approximately $6,400 during 2013. We must also pay a pro-rata portion of the electricity cost of the building. We believe both 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 MKT 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 MKT under the trading symbol NEOP. Prior to being listed on the NYSE MKT 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 2012:		
First Quarter	$3.55	$2.60
Second Quarter	3.79	2.60
Third Quarter	4.77	2.28
Fourth Quarter	2.98	2.14
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

As of March 1, 2013, we had approximately 701 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.

During the three-month period ended December 31, 2012, Platinum Montaur Life Sciences, LLC (Montaur) exercised 6,000,000 Series W warrants in exchange for issuance of 6,000,000 shares of our common stock, resulting in gross

proceeds of $1,920,000. The issuance of the shares was exempt from registration under Sections 4(2) of the Securities Act and Regulation D promulgated thereunder.

Also during the three-month period ended December 31, 2012, 1,000 shares of the Series C Convertible Preferred Stock automatically converted into 3,226,000 shares of our common stock. The issuance of the shares was exempt from registration under Sections 4(2) of the Securities Act and Regulation D promulgated thereunder.

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, 2007 through December 31, 2012. This graph assumes an investment in the Company's common stock and the indices of $100 on December 31, 2007 and that all dividends were reinvested.

	Cumulative Total Return as of December 31,					
	2007	2008	2009	2010	2011	2012
Navidea Biopharmaceuticals	$100.00	$199.30	$426.57	$720.28	$916.08	$989.51
Russell 3000	100.00	62.69	80.46	94.08	95.05	110.65
NASDAQ Biotechnology	100.00	93.40	103.19	113.89	129.12	163.33

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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 2012 and prior periods reflect the disposition of our gamma detection device 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,				
	2012	2011	2010	2009	2008
Statement of Operations Data:					
Revenue	$79	$598	$617	$—	$—
Research and development expenses	16,890	15,154	8,941	4,380	3,756
Selling, general and administrative expenses	11,178	9,548	4,353	3,028	2,936
Loss from operations	(27,989)	(24,104)	(12,677)	(7,408)	(6,692)
Other expenses, net	(1,168)	(943)	(43,567)	(35,891)	(2,124)
Benefit from income taxes	—	7,880	2,135	1,256	1,241
Loss from continuing operations	(29,157)	(17,167)	(54,109)	(42,043)	(7,575)
Discontinued operations, net of tax effect	—	22,780	4,144	2,437	2,409
Net (loss) income	(29,157)	5,613	(49,965)	(39,606)	(5,166)
Preferred stock dividends	(43)	(100)	(8,207)	(240)	—
(Loss) income attributable to common stockholders	$(29,200)	$5,513	$(58,172)	$(39,846)	$(5,166)
(Loss) income per common share (basic and diluted):					
Continuing operations	$(0.29)	$(0.17)	$(0.77)	$(0.57)	$(0.12)
Discontinued operations	$—	$0.23	$0.05	$0.03	$0.04
(Loss) income attributable to common stockholders	$(0.29)	$0.06	$(0.72)	$(0.54)	$(0.08)
Shares used in computing (loss) income per common share: [1]					
Basic and diluted	99,060	90,509	80,726	73,772	68,594

	As of December 31,				
	2012	2011	2010	2009	2008
Balance Sheet Data:					
Total assets	$11,972	$31,194	$10,863	$9,018	$9,619
Long-term obligations	7,187	6,714	2,787	13,485	7,323
Accumulated deficit	(274,558)	(245,357)	(250,870)	(192,699)	(148,840)

(1) 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.

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. (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 have one approved product in the U.S., Lymphoseek® (technetium Tc 99m tilmanocept) Injection, a novel, receptor-targeted, small-molecule radiopharmaceutical, indicated for use in lymphatic mapping for breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Additional investigational trials in other solid tumor cancers are anticipated to provide support for expanding the utilization of Lymphoseek into multiple other cancer types. We are currently developing three other radiopharmaceutical agent platforms. NAV4694, is an F-18 radiolabeled positron emission tomography (PET) imaging agent being developed as an aid in the diagnosis of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD). NAV5001, is an Iodine-123 radiolabeled single photon emission computed tomography (SPECT) imaging agent being developed as an aid in the diagnosis of Parkinson's disease (PD) and other movement disorders, with potential additional use as a diagnostic aid in dementia. RIGScan™, is a radiolabeled monoclonal antibody being developed as a diagnostic aid for use during surgery to help surgeons locate occult or metastatic cancer, with a primary focus on colorectal cancer. All of these investigational drug products are still in development and must be cleared for marketing by the appropriate regulatory authorities 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 now-approved Lymphoseek product candidate, as well as more recently on our other pipeline programs, including NAV4694, NAV5001 and RIGScan. We expect our overall research and development expenditures to continue to be significantly higher during 2013 as compared to 2012 due to the expansion of our clinical, regulatory, and business development staff and efforts that support the commercialization of Lymphoseek, further development of Lymphoseek, NAV4694, NAV5001 and RIGScan, and the potential sourcing and development of additional pipeline product candidates. The level to which the expenditures rise will depend on how successful we are in commercializing Lymphoseek and on the extent to which we are able to execute on our strategic development initiatives.

Our efforts in 2012 and to date in 2013 have resulted in the following milestone achievements:

Corporate/Financial

- Neoprobe Corporation became Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) reflecting the Company's biopharmaceutical focus on precision diagnostics development and commercialization.
- Implemented a $50 million credit facility with Platinum-Montaur Life Sciences LLC (Montaur) in July 2012, of which $15 million is currently available, to provide flexible financial resources to fund short- and long-term development and growth plans. In December 2012, the Company drew a total of $4 million under the Montaur credit facility. Montaur also exercised certain warrants in December 2012 and March 2013, providing $1.9 million and $1.4 million in proceeds, respectively.

- Completed an underwritten public offering of 1.5 million shares of common stock in February 2013, resulting in net proceeds to the Company of approximately $4.4 million after deducting expenses associated with the offering.
- Appointed pharma industry veteran Cornelia Reininger, MD, PhD, as Chief Medical Officer to lead ongoing development of our pipeline agents, playing a key role in medical strategy, protocol design, product positioning and regulatory direction. Formerly, Dr. Reininger spearheaded development and registration of the neuroimaging agents, florbetaben for Alzheimer's disease and DaTScan™ for Parkinson's disease.
- Augmented management with the addition of key strategic positions to strengthen the Company's global regulatory, commercial and manufacturing functions including William Regan, Senior Vice President, Global Regulatory Strategy; David Pendleton, Vice President, Marketing and New Product Planning; Stephen Haber, Vice President, Development; and David Casebier, Vice President, Chemistry, Manufacturing and Control.

Pipeline

- Lymphoseek
  - Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA on March 13, 2013.
  - Submitted the Lymphoseek Marketing Authorization Application to the European Medicines Agency in December 2012.
  - Reached the interim analysis point of the NEO3-06 Phase 3 head and neck cancer study of Lymphoseek with results from the interim statistical analysis and reporting of the findings expected later in 2013.
  - Initiated a collaboration with Maimonides Medical Center on an investigator-initiated clinical trial utilizing Lymphoseek for lymphatic mapping in colorectal cancer.
  - Presented data from Lymphoseek clinical trials at more than 15 major medical meetings, including: Society of Surgical Oncology, European Society of Surgical Oncology, American Society of Clinical Oncology, Society of Nuclear Medicine, International Conference on Head and Neck Cancer, European Association of Nuclear Medicine, American Society for Radiation Oncology and Radiology Society of North America.
  - Published data from the Lymphoseek Phase 3 Clinical Trial for Intraoperative Lymphatic Mapping of Lymph Nodes in Breast Cancer Compared to Sulfur Colloid and Vital Blue Dye in the *Journal of Clinical Oncology Online (2012; e21066)*.
  - Published results from the Lymphoseek Phase 3 Clinical Trials in Melanoma in the *Annals of Surgical Oncology (DOI 10.1245/s10434-012-2612-z)*.
- NAV4694
  - Initiated a Phase 2 clinical trial of NAV4694 as an aid in diagnosing AD with the goal to compare images from subjects with probable AD with similarly aged and young healthy volunteers.
  - Presented data from the NAV4694 studies six major neurological medical meetings including: Human Amyloid Imaging meeting, Alzheimer's Disease Neuroimaging Initiative, Society of Nuclear Medicine and the Alzheimer's Association International Conference on Alzheimer's Disease.
- NAV5001
  - Licensed NAV5001, an Iodine-123 radiolabeled imaging agent being developed as a potential aid in the diagnosis of PD, dementia with Lewy Bodies and other movement disorders, thus expanding the Company's neuroimaging pipeline.
- RIGScan
  - Awarded a Small Business Innovation Research grant from the National Institutes of Health for development of a radioimmunoguided surgery agent aimed at detecting metastatic cancer, with potential for grant money up to a total of $1.5 million over three years if fully funded.

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Our Outlook

With the U.S. approval of Lymphoseek on March 13, 2013, the Company is moving forward with preparations for commercial launch in the U.S. with our marketing partner, Cardinal Health, expected in the second quarter of 2013. As such, we expect to report revenue from Lymphoseek in the second quarter of 2013. However, as we do not yet have experience and insight into the level of potential sales success we may achieve with Lymphoseek, we do not currently expect to provide revenue guidance for 2013.

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 and NAV4694 product development, and to a lesser extent, on efforts to restart active development of RIGScan. In addition, during 2012 we paid $1.8 million in option and sublicense fees ($1.1 million of which was non-cash in nature) related to a sublicense agreement with Alseres for the exclusive worldwide license of NAV5001.

We spent approximately $16.9 million, $15.2 million and $8.9 million in total on research and development activities in the years ended December 31, 2012, 2011 and 2010, 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 do not currently allocate among the various development programs that we have underway, we incurred out-of-pocket charges by program as follows:

Development Program	2012	2011	2010
Lymphoseek	$5,632,183	$5,286,395	$5,854,703
NAV4694	3,339,592	5,018,490	—
NAV5001	2,159,483	—	—
RIGScan	253,325	1,302,851	940,435

Due to the advancement of our efforts with Lymphoseek, NAV4694, NAV5001, RIGScan, and potentially other programs, we expect our total drug-related development and commercialization expenses for 2013 to increase significantly over 2012. The specific levels to which each program’s expenditures may rise will depend in part on how successful we are in commercializing Lymphoseek and on the extent to which we draw on the other financial resources we have at our disposal. In general, development expenses in 2013 for Lymphoseek are expected to decrease as compared to 2012 while expenses related to NAV4694, NAV5001 and RIGScan are all currently expected to increase in 2013 over 2012.

During 2013, we expect to incur additional development expenses related to supporting the Marketing Authorization Application (MAA) review of Lymphoseek in the EU, our NEO3-06 clinical trial and studies to support Lymphoseek in a potential post-commercialization setting, and support the other product activities related to the potential marketing registration of Lymphoseek in other markets. In addition, we expect to incur significant costs during 2013 to support our business development and commercialization activities surrounding Lymphoseek. We cannot assure you that Lymphoseek will achieve regulatory approval in the EU or any other market outside the U.S., or if approved, that it will achieve market acceptance.

We also expect to incur significant expenses for NAV4694 during 2013 related to ongoing additional Phase 2 clinical trials and the initiation of a Phase 2 clinical study in subjects with mild cognitive impairment and a pivotal Phase 3 clinical trial in subjects with AD, as well as costs for manufacturing-related activities required prior to filing for regulatory clearance to market. NAV4694 is currently not expected to contribute revenue to the Company until 2016 at the earliest. We cannot assure you that further clinical trials for this product will be successful, that the agent will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

We expect to incur significant expenses for NAV5001 during 2013 related to initiation of Phase 2 and Phase 3 clinical trials, as well as for manufacturing-related activities required to support clinical activities and to prepare to file for regulatory clearance to market. NAV5001 is not expected to generate revenue for the Company until 2016 at the earliest. We cannot assure you that clinical trials for this product will be successful, that the agent will ultimate achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

We are in the process of evaluating the business, manufacturing, development and regulatory pathways forward with respect to RIGScan. We believe that the time required for continued development, regulatory approval and commercialization of a RIGScan 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 or obtain incremental financing to fund development of the RIGS technology and cannot guarantee that 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 the FDA or the European Medicines Agency (EMA) will clear RIGScan for marketing, or that it will be successfully introduced or achieve market acceptance.

Finally, 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 our stockholders approved, the sale of the GDS Business to Devicor Medical Products, Inc. (Devicor) in August 2011 (the Asset Sale). Under the terms of the Asset Purchase Agreement (APA) with Devicor, 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 fiscal years 2012 through 2017. We did not record any royalty revenue in 2012 as Devicor did not achieve the minimum sales of gamma detection devices required to trigger such payment. 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 statements of operations have been reclassified to discontinued operations, as required. Cash flows associated with discontinued operations 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 and other revenue we have received and our operating variances focus on our radiopharmaceutical development programs and the supporting general and administrative expenses.

Years Ended December 31, 2012 and 2011

Revenue. Revenue of $60,000 during 2012 was related to reimbursement of certain Lymphoseek commercialization activities by our distribution partner, Cardinal Health. Revenue of $592,000 during 2011 was related to an Ohio Third Frontier grant to support Lymphoseek development. Additional revenue of $19,000 and $6,000 during 2012 and 2011, respectively, was related to additional Ohio Third Frontier grants to support student internships.

Research and Development Expenses. Research and development expenses increased $1.7 million, or 11%, to $16.9 million during 2012 from $15.2 million during the same period in 2011. The increase was primarily due to net increases in drug project expenses related primarily to (i) increased NAV5001 development costs of $2.2 million, including option and sublicense fees of $1.8 million ($1.1 million of which was non-cash in nature) coupled with due diligence, consulting and manufacturing-related costs, (ii) a net increase in Lymphoseek development costs of $346,000 resulting from increased manufacturing-related costs, regulatory consulting costs and filing fees related to preparation and filing of a MAA with the EMA, and consulting costs related to preparation for a potential FDA Advisory Committee meeting, offset by the $1.5 million FDA filing fee and UCSD license milestone payment related to filing the Lymphoseek NDA in 2011 coupled with decreased clinical activities, and (iii) increased license fees and consulting costs related to potential pipeline products of $192,000; offset by (iv) a net decrease in NAV4694 development costs of $1.7 million, resulting from the $5.0 million initial license fee incurred in 2011, offset by increased clinical activities, technology transfer and manufacturing-related costs, project management and consulting fees in 2012, and (v) decreased RIGScan development costs of $1.0 million, primarily related to manufacturing. The net increase in research and development expenses also included an increase in headcount and related expenses required for expanded development efforts of $1.0 million, as well as increased costs related to travel, pharmacovigilance activities, consulting, training, recruiting, general office and other expenses of $737,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $1.7 million, or 17%, to $11.2 million during 2012 from $9.5 million in 2011. The net increase was primarily due to our formation of a marketing and business development team during the second half of 2011 to prepare for the commercial launch of Lymphoseek. Increased marketing costs primarily related to the pending commercial launch of Lymphoseek of $2.5 million, increased compensation costs of $1.2 million related to increased headcount and incentive-based compensation, and increased travel, insurance, taxes and general office expenses to support the increased headcount of $538,000 were offset by a decrease in separation costs of $2.7 million related to our former President and CEO which were recorded in 2011.

Other Income (Expense). Other expense, net, was $1.2 million during 2012 as compared to $943,000 in 2011. Interest expense increased to $1.2 million during 2012 from $13,000 in 2011, due to the notes payable we entered into in December 2011 and December 2012. Of the interest expense in 2012, $545,000 was non-cash in nature related to the amortization of debt issuance costs and debt discounts resulting from the warrants issued and conversion features embedded in the December 2011 note. During 2012 and 2011, we recorded income of $32,000 and charges of $952,000, respectively, related to the changes in derivative liabilities resulting from the requirement to mark our derivative liabilities to market.

Income Taxes. An estimated tax provision of $6.7 million related to the gain on the sale of discontinued operations and $1.2 million related to income from discontinued operations was offset by an estimated tax benefit of $7.9 million related to the loss from continuing operations during 2011.

Gain on Sale of Discontinued Operations. Gain on sale of discontinued operations related to the sale of our GDS Business to Devicor was $19.5 million during 2011. The sales price of $30.3 million included a cash payment of $30.0 million and an accrued net working capital adjustment of an additional $254,000. The proceeds were offset by $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 of estimated taxes, as noted above.

Income from Discontinued Operations. The income from discontinued operations was $3.3 million, net of $1.0 million in estimated taxes, during 2011 and was primarily related to the operation of our GDS Business, which was sold to Devicor in August 2011.

Years Ended December 31, 2011 and 2010

Revenue. Revenue of $592,000 during 2011 was related to the Ohio Third Frontier grant to support Lymphoseek development. Revenue of $602,000 during 2010 was related to Ohio Third Frontier and Qualifying Therapeutic Discovery Project grants. Additional revenue of $6,000 and $15,000 during 2011 and 2010, respectively, was related to additional Ohio Third Frontier grants to support student internships.

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 NAV4694, (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 (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 MKT, 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.

Liquidity and Capital Resources

Cash balances decreased to $9.1 million at December 31, 2012 from $28.6 million at December 31, 2011. The net decrease was primarily due to cash used to fund our operations, mainly for research and development activities, coupled with $1.3 million of principal payments on our notes payable, offset by $4.0 million of cash received as proceeds from our credit facility and $2.7 million received for the exercise of warrants and stock options. The current ratio decreased to 1.7:1 at December 31, 2012 from 9.0:1 at December 31, 2011.

Operating Activities. Cash used in operations increased $7.9 million to $23.9 million during 2012 compared to $16.0 million during 2011. Cash used in operations increased $10.8 million to $16.0 million during 2011 compared to $5.2 million during 2010.

Inventory levels decreased to $298,000 at December 31, 2012 from $822,000 at December 31, 2011. Inventory decreased primarily due to the reserve or write-off of Lymphoseek inventory as a result of changes in our projections of the probability of future commercial use and the consumption of materials for previously unanticipated product development activities. Offsetting these decreases was an increase in pharmaceutical materials related to the completion of a new lot of the Lymphoseek drug substance. Inventory levels increased to $822,000 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. We expect inventory levels to increase during 2013 as we produce additional drug inventory in preparation for commercial launch and establish normal stock levels for Lymphoseek.

Prepaid expenses and other current assets increased to $1.2 million at December 31, 2012 from $555,000 at December 31, 2011, primarily due to prepayments to our third party manufacturers of Lymphoseek inventory and increased

insurance premiums paid during the fourth quarter of 2012. Prepaid expenses and other current assets increased to $555,000 at December 31, 2011 from $258,000 at December 31, 2010, primarily due to 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.

Accounts payable increased to $1.4 million at December 31, 2012 from $682,000 at December 31, 2011, primarily due to increases in NAV4694 development and Lymphoseek manufacturing activities, offset by decreases in Lymphoseek regulatory activities, coupled with normal fluctuations in timing of receipt and payment of invoices. Accrued liabilities and other decreased to $2.0 million at December 31, 2012 from $2.1 million at December 31, 2011, primarily due to payment of costs related to the separation of our former President and CEO and payment of debt issuance costs related to our convertible debt, offset by increases in NAV4694 and Lymphoseek development costs. 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. 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 NAV4694, NAV5001, RIGScan, and other potential product candidates.

Investing Activities. Investing activities used $672,000 of cash during 2012 compared to $27.2 million of cash provided during 2011 and $399,000 of cash used during 2010. 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. Capital expenditures of $663,000 during 2012 were primarily for production and laboratory equipment, software, computers, and office furniture. 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 production equipment, office furniture, software, and computers. We expect our overall capital expenditures for 2013 will increase over 2012 as we purchase equipment required for NAV4694 production and potentially expand our offices to accommodate anticipated headcount additions. Payments for patent and trademark costs were $8,000, $53,000 and $32,000 during 2012, 2011 and 2010, respectively.

Financing Activities. Financing activities provided $5.1 million of cash during 2012 compared to $11.1 million provided during 2011 and $6.3 million provided during 2010. The net $5.1 million provided by financing activities during 2012 consisted primarily of $4.0 million of proceeds from notes payable and $2.7 million of proceeds from the exercise of warrants and stock options, offset by $1.3 million of principal payments on our convertible debt, $154,000 paid for related debt issuance costs, $101,000 paid for common stock repurchased from executives, and payments of preferred stock dividends of $100,000. The net $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, and payments of preferred stock dividends of $100,000. 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, and payments of preferred stock dividends of $111,000.

Fusion Capital

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

Montaur and the Bupp Investors

In June 2010, we entered into a Securities Exchange Agreement with Montaur, pursuant to which Montaur exchanged its 10% Series A Convertible Senior Secured Promissory Note with an outstanding principal amount of $7,000,000, its 10% Series B Convertible Senior Secured Promissory Note with an outstanding principal amount of $3,000,000, and

its 3,000 shares of Series A Cumulative Convertible 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 and carries no dividend requirement. In the event of the liquidation of the Company, the holders of shares of the Series B Preferred Stock have preference over the common stock. After payment of the full liquidation preference amount to which each holder is entitled, such holders of shares of Series B Preferred Stock will not be entitled to any further participation as such in any distribution of the assets of the Company. 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 David C. Bupp, then our President and CEO, and certain members of his family (the Bupp Investors), pursuant to which the Bupp Investors exchanged their 10% Convertible Secured Promissory Note with an outstanding principal amount of $1,000,000 (the 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 had a 10% dividend rate and participated equally with our common stock in liquidation proceeds based upon the number of common shares into which the Series C Preferred Stock was convertible. The exchange of the Montaur Notes, the Series A Preferred Stock and the 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.

In May 2011, Montaur converted 917 shares of their Series B Preferred Stock into 2,998,590 shares of our common stock under the terms of the Series B Preferred Stock. In July 2012, Montaur converted 3,063 shares of their Series B Preferred Stock into 10,016,010 shares of our common stock under the terms of the Series B Preferred Stock. In November 2012, we entered into a Securities Exchange Agreement with Platinum Partners Value Arbitrage Fund, L.P. (Platinum), an affiliate of Montaur, pursuant to which Platinum exchanged 3,001,860 shares of our common stock owned by Platinum for 918 shares of our Series B Preferred Stock. As of December 31, 2012, there are 6,938 shares of Series B Preferred Stock outstanding which are convertible into 22,687,260 shares of our common stock.

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. During 2012, the holder of 20,000 Series V warrants exercised them in exchange for issuance of 20,000 shares of our common stock, resulting in gross proceeds of $6,200. Also during 2012, Montaur exercised 6,000,000 Series W warrants in exchange for issuance of 6,000,000 shares of our common stock, resulting in gross proceeds of $1,920,000. In March 2013, Montaur exercised 3,000,000 Series X warrants in exchange for issuance of 3,000,000 shares of our common stock, resulting in gross proceeds of $1,380,000.

In December 2012, we entered into a Waiver Agreement (the Waiver) pursuant to which Montaur and Platinum, as the sole holders of the Series B Preferred Stock, agreed to irrevocably waive the provisions set forth in the certificate of designations for the Series B Preferred Stock (the Certificate) which provided that all outstanding shares of Series B Preferred Stock would automatically convert into shares of common stock on December 31, 2012. The Waiver will remain in effect until December 31, 2013, upon which date all outstanding shares of Series B Preferred Stock will automatically convert into common stock pursuant to the terms of the Certificate. In addition, we amended the terms of Montaur's Series X warrant to extend the expiration date from April 16, 2013 to December 31, 2013. Also in December 2012, the Series C Preferred Stock held by the Bupp Investors automatically converted into 3,226,000 shares of our common stock under the terms of the Series C Preferred Stock.

2010 Public Offering

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.

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

Sale of the GDS Business

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 with Devicor, 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. The Asset Sale has allowed 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. However, the sale of the GDS Business eliminated cash flows from the sale of medical devices. In addition, we did not record any royalty revenue in 2012 as Devicor did not achieve the minimum sales of gamma detection devices required to trigger such payment.

Hercules Debt

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules), providing for a maximum borrowing of $10 million by the Company in two advances. 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, 2012 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, the Loan Agreement provided Navidea with the option to draw a second advance in the principal amount of $3,000,000 if certain conditions were met by June 30, 2012. Such conditions were not met and Hercules no longer has an obligation to provide the additional $3,000,000. The Loan Agreement provided for an interest-only period beginning on December 29, 2011 and expiring on July 1, 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. As such, a portion of the principal, net of related discounts, has been classified as a current liability as of December 31, 2012. The outstanding balance of the debt is due December 1, 2014. 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. During 2012, we paid $1.3 million of principal payments on the Hercules debt. As of December 31, 2012, the remaining outstanding principal balance of the debt was approximately $5.7 million.

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Montaur Credit Facility

In July 2012, we entered into an agreement with Montaur to provide us with a credit facility of up to $50 million. With the recent approval of Lymphoseek, Montaur is currently committed under the terms of the agreement to extend up to $35 million in debt financing to the Company at an interest rate equal to the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10.0%; or (c) the highest rate of interest then payable pursuant to the Hercules Loan Agreement plus 0.125% (effective interest rate at December 31, 2012 was 10.125%). Through March 15, 2013, we have drawn a total of $4 million under the facility. The agreement also provides for Montaur to extend an additional $15 million on terms to be negotiated. Principal amounts are due the earlier of two years from the date of draw or June 30, 2016. No conversion features or warrants are associated with the facility. During 2012, we drew a total of $4.0 million under the credit facility and recorded interest expense of $15,000. As of December 31, 2012, the total principal amount due under the credit facility was $4.0 million.

2013 Public Offering

We filed a shelf registration statement in 2011 to provide us with future funding alternatives and flexibility as we execute on our plans to achieve our product development and commercialization goals, as well as evaluating and acting on opportunities to expand our product pipeline. On January 29, 2013, Navidea entered into an underwriting agreement (the Underwriting Agreement) with Ladenburg Thalmann & Co. Inc. (the Underwriter), related to a public offering of 1,542,389 shares of the Company’s common stock at a price of $3.10 per share less underwriting discounts and commissions (the Offering). The Offering closed on February 4, 2013, following the satisfaction of customary closing conditions. The net proceeds to the Company were approximately $4.4 million after deducting expenses associated with the Offering. The Company will use the net proceeds from the offering to fund the clinical development and launch of Lymphoseek, NAV4694, NAV5001, and RIGScan, to fund other potential product pipeline opportunities, and for general corporate purposes. The Offering was made pursuant to the Company’s existing effective shelf registration statement on Form S-3.

Outlook

Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA on March 13, 2013. Our most significant near-term priority is to continue our pre-commercialization activities related to Lymphoseek with a commercial launch anticipated in the second quarter of 2013. During 2013, we expect to incur additional development expenses related to supporting the MAA review of Lymphoseek in the EU, our NEO3-06 clinical trial and studies to support Lymphoseek in a potential post-commercialization setting, and support the other product activities related to the potential marketing registration of Lymphoseek in other markets. In addition, we expect marketing expenses related to Lymphoseek to increase in preparation for the commercial launch. We also continue to assess timelines and development costs for development of NAV4694, NAV5001 and RIGScan, but expect our development costs to increase overall as we continue to grow our precision diagnostics businesses. We are

also actively evaluating a number of different product licensing and/or acquisition opportunities. Costs related to in-licensing, acquiring and developing other late-stage radiopharmaceutical candidates that 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.

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 the FDA and international regulatory bodies, the ability to procure additional pipeline development opportunities and required financial resources, and intellectual property protection.

We have developed a plan which will allow the Company to have adequate funding, and we believe that our credit facility with Montaur, anticipated revenue deriving from U.S. sales of Lymphoseek following a second quarter 2013 commercial launch, and our access to capital markets through our shelf registration provide us with access to adequate financial resources to continue to fund our business plan. However, we cannot assure you that Lymphoseek will generate our expected levels of sales and cash flow.

We will continue to evaluate our timelines and strategic needs, and although we have not decided whether, when or how much additional capital might be raised under the shelf registration statement or the credit facility, we will continue our efforts to maintain a strong balance sheet. 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 was effective for interim and annual reporting periods beginning after December 15, 2011 and was applied prospectively. ASU 2011-04 did not have a material effect on our consolidated financial statements.

Critical Accounting Policies

We base our management's discussion and analysis of financial condition and results of operations, as well as disclosures included elsewhere in this Annual Report on Form 10-K, upon our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We describe our significant accounting policies in the notes to the audited consolidated financial statements contained elsewhere in this Annual Report on Form 10-K. We include within these policies our "critical accounting policies." Critical accounting policies are those policies that are most important to the preparation of our consolidated financial statements and require management's most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Changes in estimates and assumptions based upon actual results may have a material impact on our results of operations and/or 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. We also recognize revenue from the reimbursement by our partners of certain expenditures for which the Company has principal responsibility.

Research and Development. Research and development (R&D) expenses include both internal R&D activities and external contracted services. Internal R&D activity expenses include salaries, benefits, and stock-based compensation, as well as travel, supplies, and other costs to support our R&D staff. External contracted services include clinical trial activities, CMC-related activities, and regulatory costs. R&D expenses are charged to operations as incurred. We review and accrue R&D expenses based on services performed and rely upon estimates of those costs applicable to the stage of completion of each project.

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 and the portion that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. The determination of fair value using the Black-Scholes option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option behaviors. We estimate the expected term based on the contractual term of the awards and employees' exercise and expected post-vesting termination behavior. The restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award.

Since stock-based compensation is recognized only for those awards that are ultimately expected to vest, we have applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

- *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. 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.

Contractual Obligations and Commercial Commitments

The following table presents our contractual obligations and commercial commitments as of December 31, 2012.

Payments Due By Period

Contractual Cash Obligations	Total	2013	2014	2015	2016	2017 and After
Capital lease obligation	$17,399	$8,789	$3,039	$3,039	$2,532	$ —
Operating leases	215,173	196,068	19,105	—	—	—
Unconditional purchase obligations (a)	119,375	119,375	—	—	—	—
Principal and interest on short-term debt	243,600	243,600	—	—	—	—
Principal and interest on long-term debt	11,425,075	3,586,783	7,838,292	—	—	—
Total contractual cash obligations	$12,020,622	$4,154,615	$7,860,436	$3,039	$2,532	$ —

(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 12 months.

* This table does not include obligations such as license agreements, contracted services, or employment agreements as such obligations are dependent upon performance conditions.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of December 31, 2012, our $9.1 million in cash was primarily invested in interest-bearing money market accounts. Due to the low interest rates being realized on these 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.

We also have exposure to changes in interest rates on our variable-rate debt obligations. As of December 31, 2012, the interest rate on the majority of our debt obligations was based on the U.S. prime rate. Based on the amount of our variable rate borrowings at December 31, 2012, which totaled approximately $9.7 million, an immediate one percentage point increase in the U.S. prime rate would increase our annual interest expense by approximately $100,000. This estimate assumes that the amount of variable rate borrowings remains constant for an annual period and that the interest rate change occurs at the beginning of the period. Because our debt obligations are currently subject to the minimum interest rates defined in the loan agreements, a decrease in the U.S. prime rate would not affect our annual interest expense.

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, 2012, 2011 and 2010, we recorded approximately $15,000, $3,000 and $3,000 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 using various inputs and assumptions, one of which is the market price of Company stock. As of December 31, 2012, we did not have any derivative liabilities recorded on our balance sheet. As such, we do not believe we are exposed to any equity price risk related to derivative instruments.

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 18, 2013 are set forth at pages F-1 through F-26 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, 2012. 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, 2012. 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, 2012, 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 61.

Changes in Internal Control Over Financial Reporting

During the year ended December 31, 2012, 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 internal control over financial reporting as of December 31, 2012, 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, 2012, 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, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012 and our report dated March 18, 2013 expressed an unqualified opinion on those consolidated financial statements.

/s/ BDO USA, LLP

Chicago, Illinois

March 18, 2013

Item 9B. Other Information.

None.

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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.	59	Audit; Compensation, Nominating and Governance (Chairman)
Brendan A. Ford	54	Audit (Chairman); Compensation, Nominating and Governance
Jess Emery Jones, M.D.	34	Audit; Compensation, Nominating and Governance
Mark J. Pykett, V.M.D., Ph.D.	49	—
Eric K. Rowinsky, M.D.	56	—
Gordon A. Troup	59	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, marketing, 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, strategic alliances, 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 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 Science and Research and Compensation Committees 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:

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 served as President and Chief Executive Officer of Navidea since April 2011 and as a director of Navidea since August 2011. He has more than 16 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.

Directors whose terms continue until the 2015 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 is a board member of Trustmark Insurance, a mutual insurance company; Enzymedica, Inc., a private nutraceutical company; and Sequoia Sciences, Inc., a private biotechnology company. Dr. Drake received his undergraduate degree from Bowdoin College, and his Ph.D. in neurobiology and biochemistry from Bryn Mawr College.

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 for 3 years by Zellerbach Paper, a Mead Company. Mr. Troup is currently a partner and Chairman of the Board of Scioto Properties, LLC, a provider of group homes to the developmentally disabled nationwide and Chairman of the Advisory Board of Guild Associates, Inc., a chemical engineering and research and development company serving the energy and military community. Mr. Troup has a B.S. degree in Business Management from San Diego State

University.

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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
Frederick O. Cope, Ph.D.	66	Senior Vice President, Pharmaceutical Research and Clinical Development
Brent L. Larson	49	Senior Vice President; Chief Financial Officer; Treasurer and Secretary
William J. Regan	61	Senior Vice President, Global Regulatory Strategy
Cornelia B. Reininger, M.D., Ph.D.	60	Senior Vice President and Chief Medical Officer
Thomas H. Tulip, Ph.D.	60	Executive Vice President and Chief Business Officer

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 was 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.

William J. Regan has served as Senior Vice President, Global Regulatory Strategy of Navidea since October 2012. Prior to accepting his position with Navidea, Mr. Regan served as a consultant to Navidea from July 2011 to September 2012. As Principal of Regan Advisory Services (RAS) from September 2006 to September 2012, Mr. Regan consulted on all aspects of regulatory affairs within pharmaceutical, biotechnology and diagnostic imaging businesses, including PET diagnostic agents (cardiovascular, neurology, and oncology), contrast agents, and radiopharmaceuticals. Previous to RAS, Mr. Regan held roles of increasing responsibility in radiopharmaceutical manufacturing, quality assurance, pharmaceutical technology and regulatory affairs at Bristol-Myers Squibb (BMS). From September 2001 to August 2006, he served as global regulatory head for BMS' Medical Imaging business where he was responsible for all regulatory aspects of the company's in-market and pipeline products and led regulatory actions resulting in product approvals. Mr. Regan has been an active member in the Society of Nuclear Medicine, Council on Radionuclides and Radiopharmaceuticals (CORAR), and Medical Imaging and Technology Alliance, and formerly served as the industry chair of the Regulatory and Clinical Practice committee on behalf of CORAR. Mr. Regan holds a B.A. in Chemistry from Rutgers University.

Cornelia B. Reininger, M.D., Ph.D., has served as Senior Vice President and Chief Medical Officer of Navidea since November 2012. Prior to accepting her position with Navidea, Dr. Reininger served as the Senior Director of Clinical Research and Global Clinical Leader of Bayer Healthcare Pharmaceuticals' beta-amyloid PET development programs from November 2007 to October 2012. Dr. Reininger also served in roles of increasing responsibility with the global medical organizations of GE Healthcare and Amersham Health – Diagnostic Imaging from April 2001 to October 2007. Dr. Reininger holds an Associate Professor of Surgery and External Lecturer position at Ludwig Maximillian University (LMU) in Munich, Germany, where she completed her medical education and residency in general and vascular surgery. During her residency, she was on staff at the LMU Downtown Surgical Hospital and Outpatient Clinic, rotating as Chief Resident in vascular surgery and the intensive care unit. She later became the head of the hospital's thrombosis research laboratory. Dr. Reininger is a member of the Society of Nuclear Medicine and the European Association of Nuclear Medicine.

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, 2012, except for: (i) Mark J. Pykett, V.M.D., Ph.D., who had one late Form 4 filing related to Company stock that he purchased on the open market in September 2012, and (ii) Gordon A. Troup, who had one late Form 4 filing related to Company stock that he purchased on the open market in August 2012.

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 16 meetings in the fiscal year ended December 31, 2012, 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 2012 Annual Meeting of Stockholders in person, except for Jess Jones, M.D., who participated telephonically due to travel delays.

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 MKT 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, 2012. 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 one meeting in the fiscal year ended December 31, 2012 to complement compensation-related discussions held by the full Board. 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, and the CNG Committee's commitment to pay for performance, 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 ("say-on-pay") 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). At the Annual Meeting of Stockholders held on August 15, 2011, approximately 72% of our stockholders voted in favor of the resolution relating to the compensation of our Named Executive Officers. The CNG Committee believes this affirmed stockholders' support of the Company's executive compensation program, and as such did not change its approach in 2012. The CNG Committee will continue to consider the results of future say-on-pay votes when making future compensation decisions for the executive officers.

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. Dr. Pykett provides input for the CNG Committee regarding the performance and appropriate compensation of the other officers. The CNG Committee gives considerable weight to Dr. Pykett's evaluation of the other officers because of his direct knowledge of each officer's performance and contributions. 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 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. Pearl Meyer's study did not raise any concerns regarding conflicts of interest.

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, in 2012 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 operate within the biotechnology industry, have market capitalization between $100 million and $500 million, 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:

Argule Inc.

Cell Therapeutics Inc.

Celldex Therapeutics Inc.

Curis Inc.

Exact Sciences Corp.

Immunomedics Inc.

Infinity Pharmaceuticals 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 and short-term and long term incentive plans 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 2012 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.

In setting specific base salaries for fiscal 2012, the CNG Committee considered published proxy data for similar positions at peer group companies.

The following table shows the increases in base salaries for the Named Executive Officers that were approved for fiscal 2012 compared to the approved salaries for fiscal 2011:

Named Executive Officer	Fiscal 2012 Base Salary	Fiscal 2011 Base Salary	**Increase** [a]	
Mark J. Pykett, V.M.D., Ph.D.	425,000	375,000	13.3	%
Rodger A. Brown	191,000	185,000	3.2	%
Frederick O. Cope, Ph.D.	271,000	265,000	2.3	%
Brent L. Larson	265,000	250,000	6.0	%
Thomas H. Tulip, Ph.D. [b]	325,000	300,000	8.3	%

(a) 2012 salary increases reflect both merit increases and market adjustments that the CNG Committee felt were necessary to remain competitive in the life sciences industry.

(b) Dr. Tulip's salary was increased to $325,000 effective June 1, 2012. The amount shown for fiscal 2012 is the approved annual salary of Dr. Tulip in effect at the end of 2012. The actual amount paid to Dr. Tulip during fiscal 2012 is shown under "Salary" in the Summary Compensation table below.

The CNG Committee has approved the following base salaries for fiscal 2013: Dr. Pykett, $425,000; Mr. Brown, $203,000; Dr. Cope, $271,000; Mr. Larson, $265,000; and Dr. Tulip, $325,000.

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. Cash bonus targets for senior executives are determined as a percentage of base salary, based on published proxy data for similar positions at peer group companies. 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.

In April 2012, the CNG Committee established the fiscal 2012 targets and performance measures for all Company employees. For fiscal 2012, 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 2012) and certain business performance objectives, weighted as a percentage of the total target amount. The business performance objectives established for fiscal 2012 were as follows:

- Approval of the Company's Lymphoseek product by the United States Food and Drug Administration (FDA) and initiation of the commercial launch of Lymphoseek in the United States, subject to maximum 30% reduction of bonus if not achieved.

- Commencement of a Phase 2 or Phase 3 clinical study for NAV4694, 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 Alzheimer's disease licensed by the Company from AstraZeneca AB, subject to maximum 15% reduction of bonus if not achieved.
- Submission to the European Medicines Agency (EMA) of an application for marketing authorization for Lymphoseek in the European Union, subject to maximum 10% reduction of bonus if not achieved.

- Completion of an in-license or product acquisition transaction for the addition of a candidate to the Company's development pipeline, subject to maximum 10% reduction of bonus if not achieved.
- Discretionary bonus, equal to 35% of the total bonus objective.

For the Named Executive Officers, the CNG Committee established the following cash bonus targets for fiscal 2012:

Named Executive Officer	Target Cash Bonus (% of Salary)		Target Cash Bonus ($ Amount)
Mark J. Pykett, V.M.D., Ph.D.	50.0	%	$ 212,500
Rodger A. Brown	20.0	%	38,200
Frederick O. Cope, Ph.D.	25.0	%	67,750
Brent L. Larson	27.5	%	72,875
Thomas H. Tulip, Ph.D. [(a)]	35.0	%	105,000

(a) Effective June 1, 2012, Dr. Tulip entered into a new employment agreement, authorized by the Board of Directors, which provides for a maximum cash bonus amount of 35.0% of Dr. Tulip's new annual salary. Dr. Tulip's maximum cash bonus amount for 2012 was pro-rated based on time served at each salary level during the 2012 calendar year.

In February 2013, the CNG Committee determined the extent to which the Company's goals were achieved during 2012. With respect to the first objective, the Company did not obtain FDA approval for Lymphoseek and the product was not commercially launched, therefore the Committee concluded that the goal was not achieved, resulting in a 30% reduction in the target bonus amount. With regard to the second objective, the Committee concluded that the commencement of a Phase 2 trial for NAV4694 in September 2012 evidenced the successful achievement of that goal. With regard to the third objective, the Committee determined that the submission of a marketing authorization application for Lymphoseek to the EMA in December 2012 evidenced the successful achievement of that goal. With regard to the fourth objective, the Committee concluded that the in-licensing of NAV5001 from Alseres Pharmaceuticals, Inc. in July 2012 constituted the successful achievement of that goal. With respect to the 35% discretionary portion, the Company's overall performance and accomplishments 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, paid in February 2013, are shown under "Non-Equity Incentive Plan Compensation" in the Summary Compensation table below.

Also in February 2013, the CNG Committee established the fiscal 2013 targets and performance measures for all Company employees. For fiscal 2013, the cash bonus for each executive officer will be a function of the designated target bonus amount (stated as a percentage of base salary to be pro-rated based on time served at each salary level during fiscal 2013) and certain business performance objectives, weighted as a percentage of the total target amount. The business performance objectives established for fiscal 2013 are as follows:

- Approval of the Company’s Lymphoseek product by the FDA, initiation of the commercial launch of Lymphoseek in the United States, and achievement of a targeted amount of revenues from sales, subject to maximum 35% reduction of bonus if not achieved.
- Submission of supplemental New Drug Application for Lymphoseek to the FDA, subject to maximum 15% reduction of bonus if not achieved.
- Commencement of a Phase 3 pivotal study for NAV4694, 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 Alzheimer's, subject to maximum 10% reduction of bonus if not achieved.
- Commencement of a Phase 3 pivotal study for NAV5001, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson’s disease and other movement disorders, with a potential use as a diagnostic aid in dementia, subject to maximum 10% reduction of bonus if not achieved.

- Discretionary bonus, equal to 30% of the total bonus objective.

The CNG Committee has approved the following target cash bonus amounts (stated as a percentage of base salary to be pro-rated based on time served at each salary level during fiscal 2013) for the Named Executive Officers for fiscal 2013: Dr. Pykett, 50.0%; Dr. Cope, 25.0%; Mr. Larson, 27.5%; Mr. Regan, 25.0%; Dr. Reininger, 30.0%; and Dr. Tulip, 35.0%.

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. Equity awards for senior executives are determined as a percentage of base salary, based on published proxy data for similar positions at peer group companies. Stock option awards have vesting schedules over several years to promote long-term performance and retention of the recipient, and restricted stock awards may include specific performance criteria for vesting or vest over a specified period of time.

On February 17, 2012, the Company granted 300,000 shares of restricted stock to Mark J. Pykett. Dr. Pykett's restricted stock will vest as to one-third of the shares on the first three anniversaries of the date of grant, 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 agreement all restricted shares that have not vested at the effective date of Dr. Pykett's termination shall immediately be forfeited by Dr. Pykett.

Also on February 17, 2012, the Company granted options to purchase shares of common stock of the Company to all Company employees, including the Named Executive Officers. The stock options have an exercise price of $3.28 vest as to one-fourth of the shares 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 the Named Executives 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 the Named Executive's termination shall immediately vest and become exercisable. The following number of options was granted to each Named Executive Officer: Dr. Pykett, 250,000; Mr. Brown, 65,000; Dr. Cope, 127,000; Mr. Larson, 88,000; and Dr. Tulip, 163,000.

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.

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. Effective January 1, 2012, Dr. Pykett's annual base salary was increased to $425,000. For the calendar year ending December 31, 2012, the CNG Committee determined that the maximum bonus payment to Dr. Pykett will be $212,500.

Frederick O. Cope, Ph.D. Dr. Cope is employed under a 24-month employment agreement effective January 1, 2013. 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. Effective January 1, 2012, Dr. Cope's annual base salary was increased to $271,000. For the calendar year ending December 31, 2012, the CNG Committee determined that the maximum bonus payment to Dr. Cope will be $67,750.

Brent L. Larson. Mr. Larson is employed under a 24-month employment agreement effective January 1, 2013. 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. Effective January 1, 2012, Mr. Larson's annual base salary was increased to $265,000. For the calendar year ending December 31, 2012, the CNG Committee determined that the maximum bonus payment to Mr. Larson will be $72,875.

William J. Regan. Mr. Regan is employed under a 12-month employment agreement effective October 1, 2012. The employment agreement provides for an annual base salary of $250,000. For the calendar year ending December 31, 2012, the CNG Committee determined that the maximum bonus payment to Mr. Regan will be $28,125.

Cornelia B. Reininger, M.D., Ph.D. Dr. Reininger is employed under a 17-month employment agreement effective November 1, 2012. The employment agreement provides for an annual base salary of $300,000. For the calendar year ending December 31, 2012, the CNG Committee determined that the maximum bonus payment to Dr. Reininger will be $15,041.

Thomas H. Tulip, Ph.D. Dr. Tulip is employed under a 24-month employment agreement effective June 1, 2012. The employment agreement provides for an annual base salary of $325,000. For the calendar year ending December 31, 2012, the CNG Committee has determined that the maximum bonus payment to Dr. Tulip will be $113,750, to be pro-rated based on time served at each salary level during the 2012 calendar year.

Post-Employment Compensation

The following tables set forth the expected benefit to be received by each of our Named Executive Officers in the event of his termination resulting from various scenarios, assuming a termination date of December 31, 2012 and a stock price of $2.83, our closing stock price on 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)	—	—	—	210,100	—	—	—
Paid time off (c)	8,173	8,173	8,173	8,173	8,173	8,173	8,173
2012 401(k) match (d)	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Continuation of benefits (e)	—	—	22,870	22,870	—	34,305	22,870
Stock option vesting acceleration (f)	—	—	—	—	150,666	150,666	150,666
Restricted stock vesting acceleration (g)	—	—	—	—	—	990,150	1,838,850
Total	$13,173	$13,173	$36,043	$246,143	$632,589	$1,657,044	$2,963,059

(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 40 hours of accrued but unused vacation time as of December 31, 2012.

(d) Amount represents the value of 1,649 shares of Company stock which was accrued during 2012 as the Company's 401(k) matching contribution but was unissued as of December 31, 2012.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2012, except in the case of termination without cause, when the amount represents 18 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2012.

(f) 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 $2.83, the closing price of the Company's stock on December 31, 2012, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.83, the closing price of the Company's stock on December 31, 2012.

(g) 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)	—	—	—	93,100	—	—	—
Paid time off (c)	3,673	3,673	3,673	3,673	3,673	3,673	3,673

2012 401(k) match (d)	—	—	—	—	—	—	—
Continuation of benefits (e)	—	—	16,304	16,304	—	16,304	16,304
Stock option vesting acceleration (f)	—	—	—	—	27,900	27,900	27,900
Restricted stock vesting acceleration (g)	—	—	—	—	—	—	70,725
Total	$ 3,673	$ 3,673	$19,977	$113,077	$196,573	$212,877	$366,102

(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 40 hours of accrued but unused vacation time as of December 31, 2012.

(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, 2012.

(f) 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 $2.83, the closing price of the Company's stock on December 31, 2012, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.83, the closing price of the Company's stock on December 31, 2012.

(g) 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)	—	—	—	133,100	—	—	—
Paid time off (c)	2,085	2,085	2,085	2,085	2,085	2,085	2,085
2012 401(k) match (d)	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Continuation of benefits (e)	—	—	16,304	16,304	—	16,304	16,304
Stock option vesting acceleration (f)	—	—	—	—	55,800	55,800	55,800
Restricted stock vesting acceleration (g)	—	—	—	—	—	—	495,075
Total	$ 7,085	$ 7,085	$23,388	$156,488	$307,885	$324,188	$941,763

(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 16 hours of accrued but unused vacation time as of December 31, 2012.

(d) Amount represents the value of 1,649 shares of Company stock which was accrued during 2012 as the Company's 401(k) matching contribution but was unissued as of December 31, 2012.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2012.

(f) 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 $2.83, the closing price of the Company's stock on December 31, 2012, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.83, the closing price of the Company's stock on December 31, 2012.

(g) 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)	—	—	—	130,100	—	—	—
Paid time off (c)	5,096	5,096	5,096	5,096	5,096	5,096	5,096
2012 401(k) match (d)	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Continuation of benefits (e)	—	—	22,870	22,870	—	22,870	22,870

Stock option vesting acceleration (f)	—	—	—	—	44,175	44,175	44,175
Restricted stock vesting acceleration (g)	—	—	—	—	—	—	212,175
Total	$ 10,096	$ 10,096	$32,966	$163,066	$261,271	$284,141	$599,816

(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 40 hours of accrued but unused vacation time as of December 31, 2012.

(d) Amount represents the value of 1,649 shares of Company stock which was accrued during 2012 as the Company's 401(k) matching contribution but was unissued as of December 31, 2012.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2012.

(f) 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 $2.83, the closing price of the Company's stock on December 31, 2012, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.83, the closing price of the Company's stock on December 31, 2012.

(g) 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)	$ —	$ —	$—	$—	$325,000	$325,000	$487,500
Disability supplement (b)	—	—	—	160,100	—	—	—
Paid time off (c)	6,250	6,250	6,250	6,250	6,250	6,250	6,250
2012 401(k) match (d)	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Continuation of benefits (e)	—	—	—	—	—	—	—
Stock option vesting acceleration (f)	—	—	—	—	—	—	—
Restricted stock vesting acceleration (g)	—	—	—	—	—	—	—
Total	$ 11,250	$ 11,250	$11,250	$171,350	$336,250	$336,250	$498,750

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

(b) 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.

(c) Amount represents the value of 40 hours of accrued but unused vacation time as of December 31, 2012.

(d) Amount represents the value of 1,649 shares of Company stock which was accrued during 2012 as the Company's 401(k) matching contribution but was unissued as of December 31, 2012.

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

(f) 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 $2.83, the closing price of the Company's stock on December 31, 2012, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.83, the closing price of the Company's stock on December 31, 2012.

(g) 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., and each served as a member of the CNG Committee during the last completed fiscal year. None of these individuals were at any time during the fiscal year ended December 31, 2012, or at any other time, an officer or employee of the Company.

No director who served on the CNG Committee during 2012 had any relationships requiring disclosure by the Company under the SEC's rules requiring disclosure of certain relationships and related-party transactions. None of the Company's executive officers served as a director or a member of a compensation committee (or other committee serving and equivalent function) of any other entity, the executive officers of which served as a director of the Company or member of the CNG Committee during 2012.

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 2012

Named Executive Officer	Year	Salary	(a) Stock Awards	(b) Option Awards	(c) Non-Equity Incentive Plan Compensation	(d) All Other Compensation	Total Compensation
Mark J. Pykett, V.M.D., Ph.D. (e)	2012	$425,000	$983,700	$481,827	$ 140,250	$ 13,808	$ 2,044,585
President and	2011	363,249	201,450	—	175,867	4,788	745,354
Chief Executive Officer	2010	41,875	530,700	193,783	6,278	—	772,636
Rodger A. Brown	2012	$191,000	$—	$125,275	$ 25,296	$ 2,553	$ 344,124
Vice President, Global	2011	172,347	—	—	29,250	5,463	207,060
Regulatory Operations and Quality Assurance	2010	155,000	—	72,585	28,650	—	256,235
Frederick O. Cope, Ph.D.	2012	$271,000	$—	$244,768	$ 55,043	$ 11,114	$ 581,925
Senior Vice President,	2011	252,342	—	—	63,375	10,396	326,113
Pharmaceutical Research and Clinical Development	2010	211,000	—	145,169	51,375	4,751	412,295
Brent L. Larson	2012	$265,000	$—	$169,603	$ 49,555	$ 11,404	$ 495,562
Senior Vice President and	2011	222,637	—	—	43,875	8,450	274,962
Chief Financial Officer	2010	195,000	—	114,926	37,500	4,595	352,021
Thomas H. Tulip, Ph.D. (f)	2012	$314,583	$—	$314,151	$ 75,075	$ 9,615	$ 713,424
Executive Vice President and	2011	175,000	394,320	346,842	60,023	5,708	981,893
Chief Business Officer	2010	—	—	—	—	—	—

(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 2012, 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) Dr. Pykett commenced employment with the Company effective November 15, 2010, and was promoted to President and Chief Executive Officer effective April 15, 2011.

(f) 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 2012

Named Executive Officer	Year	(a) Payment for Unused Vacation	(b) Reimbursement of Additional Tax Liability Related to Health Insurance Premiums	(c) 401(k) Plan Employer Matching Contribution	Total All Other Compensation
Mark J. Pykett, V.M.D., Ph.D. (d)	2012	$ 7,212	$ 1,596	$ 5,000	$ 13,808
	2011	—	1,019	3,769	4,788
	2010	—	—	—	—
Rodger A. Brown	2012	$ 1,512	$ 1,041	$ —	$ 2,553
	2011	4,769	694	—	5,463
	2010	—	—	—	—
Frederick O. Cope, Ph.D.	2012	$ 5,096	$ 1,018	$ 5,000	$ 11,114
	2011	4,818	678	4,900	10,396
	2010	—	—	4,751	4,751
Brent L. Larson	2012	$ 4,808	$ 1,596	$ 5,000	$ 11,404
	2011	2,531	1,019	4,900	8,450
	2010	—	—	4,595	4,595
Thomas H. Tulip, Ph.D. (e)	2012	$ 4,615	$ —	$ 5,000	$ 9,615
	2011	—	2,807	2,901	5,708
	2010	—	—	—	—

(a) Amount represents payment for unused vacation time in excess of the amount eligible for rollover in fiscal 2012. 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 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.

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

(e) 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 2012. 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 2012

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	
Mark J. Pykett, V.M.D., Ph.D.	N/A	$ —	$ 212,500	—	—	—	—	$ —	$ —	(a)
	2/17/2012	$ —	$ —	—	—	300,000	—	$ —	$ 983,700	(c)
	2/17/2012	$ —	$ —	—	—	—	250,000	$ 3.28	$ 481,827	(d)
Rodger A. Brown	N/A	$ —	$ 38,200	—	—	—	—	$ —	$ —	(a)
	2/17/2012	$ —	$ —	—	—	—	65,000	$ 3.28	$ 125,275	(d)
Frederick O. Cope, Ph.D.	N/A	$ —	$ 67,750	—	—	—	—	$ —	$ —	(a)
	2/17/2012	$ —	$ —	—	—	—	127,000	$ 3.28	$ 244,768	(d)
Brent L. Larson	N/A	$ —	$ 72,875	—	—	—	—	$ —	$ —	(a)
	2/17/2012	$ —	$ —	—	—	—	88,000	$ 3.28	$ 169,603	(d)
Thomas H. Tulip, Ph.D.	N/A	$ —	$ 110,130	—	—	—	—	—	$ —	(a)
	2/17/2012	$ —	$ —	—	—	—	163,000	$ 3.28	$ 314,151	(d)

(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, pro-rated based on time served at each salary level during the 2012 fiscal year. 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 as to one-third on each of the first three anniversaries of the date of grant 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 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 the Named Executive Officer 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 Agreements all stock options that have not vested at the effective date of the Named Executive Officer'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, 2012.

Outstanding Equity Awards Table at Fiscal 2012 Year-End

	Option Awards					Stock Awards		Equity Incentive Plan Awards		
Named	Number of Securities Underlying Unexercised Options (#)		Option Exercise	Option Expiration		Number of Shares of Stock that Have Not	Market Value of Shares of Stock that Have Not	Number of Unearned	Market Value of Unearned	
Executive Officer	Exercisable	Unexercisable	Price	Date	Note	Vested	Vested	Shares	Shares (u)	Note
Mark J. Pykett, V.M.D., Ph.D.	133,334	66,666	$1.70	11/12/2020	(j)			300,000	$849,000	(q)
	—	250,000	$3.28	2/17/2022	(m)			50,000	$141,500	(r)
						300,000	$849,000			(t)
Rodger A. Brown	50,000	—	$0.49	7/28/2014	(b)			20,000	$56,600	(n)
	40,000	—	$0.39	12/10/2014	(c)			25,000	$70,750	(p)
	20,000	—	$0.26	12/27/2015	(d)					
	20,000	—	$0.27	12/15/2016	(e)					
	20,000	—	$0.362	1/3/2018	(f)					
	25,000	—	$0.59	1/5/2019	(g)					
	50,000	—	$1.10	10/30/2019	(i)					
	30,000	30,000	$1.90	12/21/2020	(k)					
	—	65,000	$3.28	2/17/2022	(m)					
Frederick O. Cope, Ph.D.	50,000	—	$0.65	2/16/2019	(h)			100,000	$283,000	(o)
	75,000	—	$1.10	10/30/2019	(i)			75,000	$212,250	(p)
	60,000	60,000	$1.90	12/21/2020	(k)					
	—	127,000	$3.28	2/17/2022	(m)					
Brent L. Larson	70,000	—	$0.30	1/7/2014	(a)			50,000	$141,500	(n)
	50,000	—	$0.49	7/28/2014	(b)			75,000	$212,250	(p)

	50,000	—	$0.39	12/10/2014	(c)			
	40,000	—	$0.26	12/27/2015	(d)			
	50,000	—	$0.27	12/15/2016	(e)			
	50,000	—	$0.362	1/3/2018	(f)			
	25,000	—	$0.59	1/5/2019	(g)			
	75,000	—	$1.10	10/30/2019	(i)			
	47,500	47,500	$1.90	12/21/2020	(k)			
	—	88,000	$3.28	2/17/2022	(m)			
Thomas H. Tulip, Ph.D.	27,500	82,500	$4.93	6/1/2021	(l)	60,000	$169,800	(s)
	—	163,000	$3.28	2/17/2022	(m)			

(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 vested as to one-third on each of the first three anniversaries of the date of grant.

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

(i) Options were granted 10/30/2009 and vested 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) Options were granted 2/17/2012 and vest as to one-fourth on each of the first four anniversaries of the date of grant.

(n) 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 the 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.

(o) 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 the FDA or the approval of marketing authorization for Lymphoseek by the 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.

(p) 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 the FDA or the approval of marketing authorization for Lymphoseek by the 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.

(q) 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 the FDA or the approval of marketing authorization for Lymphoseek by the EMA and 175,000 of the restricted shares will vest upon the approval of a NDA for a RIGS technology product by the FDA or the approval of marketing authorization for a RIGS technology product by the 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.

(r) 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 the FDA or the 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.

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

employment of Dr. Tulip with the Company is terminated 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.

(t) Restricted shares granted February 17, 2012. Pursuant to the terms of the restricted stock agreement between the Company and Dr. Pykett, the restricted shares will vest as to one-third on each of the first three anniversaries of the date of grant. 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.

(u) Estimated by reference to the closing market price of the Company's common stock on December 31, 2012, 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, 2012, was $2.83.

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 2012.

Options Exercised and Stock Vested Table for Fiscal 2012

	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)
Mark J. Pykett, V.M.D., Ph.D.	—	—	—	—
Rodger A. Brown	—	—	—	—
Frederick O. Cope, Ph.D.	—	—	—	—
Brent L. Larson	—	—	—	—
Thomas H. Tulip, Ph.D.	—	—	—	—

(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.

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, 2012. The Chairman of the Company's Board of Directors received an additional annual retainer of $25,000, the Chairman of the Audit Committee received an additional annual retainer of $10,000, and the Chairman of the CNG Committee received an additional annual retainer of $7,500 for their services in those capacities during 2012. Members of both 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 2012.

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 first anniversary of the date of grant. The aggregate number of equity awards outstanding at February 28, 2013 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, 2012.

Name	(a) Fees Earned or Paid in Cash	(b),(c) Option Awards	(d),(e) Stock Awards	All Other Compensation	Total Compensation
Peter F. Drake, Ph.D.	$ 48,500	$—	$46,733	$ —	$ 95,233
Brendan A. Ford	52,000	—	46,733	—	98,733
Jess Emery Jones, M.D.	39,500		46,733	—	86,233
Eric K. Rowinsky, M.D.	37,000	—	46,733	—	83,733
Eric K. Rowinsky, M.D. (f)	—	21,311	—	105,000	126,311
Gordon A. Troup	67,000	—	46,733	—	113,733

(a) Amount represents fees earned during the fiscal year ended December 31, 2012 (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, 2012, the non-employee directors held an aggregate of 93,764 options to purchase shares of common stock of the Company. Dr. Rowinsky held 73,764 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) During the year ended December 31, 2012, the non-employee directors were issued an aggregate of 85,000 shares of restricted stock which vest as to 100% of the shares on the first anniversary of the date of grant. At December 31, 2012, the non-employee directors held an aggregate of 260,000 shares of unvested restricted stock. Messrs. Ford and Troup and Dr. Rowinsky each held 64,000 shares of unvested restricted stock, and Drs. Drake and Jones each held 34,000 shares of unvested restricted stock.

(f) 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, 2012, Dr. Rowinsky earned a total of $105,000 in cash consulting fees, and was issued 13,764 options to purchase shares of common stock of the Company.

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

Equity Compensation Plan Information

The following table sets forth additional information as of December 31, 2012, 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)]	3,412,777	$ 2.01	3,219,130
Equity compensation plans not approved by security holders	—	—	—
Total	3,412,777	$ 2.01	3,219,130

(1) Our stockholders ratified the Fourth Amended and Restated 2002 Stock Incentive Plan (the Plan) at the 2012 Annual Meeting of Stockholders held on August 14, 2012, which increased the total number of shares available for grant under the Plan to 12,000,000 shares.

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

The following table sets forth, as of February 28, 2013, 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	365,471	(a)		(n)
Frederick O. Cope, Ph.D.	228,811	(b)		(n)
Peter F. Drake, Ph.D.	27,000	(c)		(n)
Brendan A. Ford	72,000	(d)		(n)
Jess Emery Jones, M.D.	17,000	(e)		(n)
Brent L. Larson	777,250	(f)		(n)
Mark J. Pykett, V.M.D., Ph.D.	270,432	(g)		(n)
Cornelia B. Reininger, M.D., Ph.D.	—	(h)		(n)
Eric K. Rowinsky, M.D.	165,764	(i)		(n)
Gordon A. Troup	97,000	(j)		(n)
Thomas H. Tulip, Ph.D.	96,690	(k)		(n)
All directors and executive officers as a group (12 persons)	2,158,418	(l)(o)	1.9	%
Platinum Montaur Life Sciences, LLC	10,728,324	(m)	9.4	%

(*) 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 271,250 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 158,750 shares issuable upon exercise of options which are not exercisable within 60 days. Mr. Brown was one of the Company's three most highly compensated officers, other than the Company's Principal Executive Officer (PEO) and Principal Financial Officer (PFO), during the fiscal year ended December 31, 2012. However, as a result of management additions which occurred during 2012, Mr. Brown is not an executive officer for the fiscal year ending December 31, 2013.

(b) This amount includes 216,750 shares issuable upon exercise of options which are exercisable within 60 days and 7,061 shares in Dr. Cope's account in the 401(k) Plan, but it does not include 175,000 shares of unvested restricted stock and 300,250 shares issuable upon exercise of options which are not exercisable within 60 days.

(c) This amount does not include 29,250 shares of unvested restricted stock.

(d) This amount does not include 59,250 shares of unvested restricted stock.

(e) This amount does not include 29,250 shares of unvested restricted stock.

(f) This amount includes 479,500 shares issuable upon exercise of options which are exercisable within 60 days and 97,625 shares in Mr. Larson's account in the 401(k) Plan, but it does not include 125,000 shares of unvested restricted stock and 255,500 shares issuable upon exercise of options which are not exercisable within 60 days.

(g) This amount includes 195,834 shares issuable upon exercise of options which are exercisable within 60 days, 1,100 shares held in an IRA which is owned by Dr. Pykett, and 1,198 shares in Dr. Pykett's account in the 401(k) Plan, but it does not include 550,000 shares of unvested restricted stock and 558,166 shares issuable upon exercise of options which are not exercisable within 60 days.

(h) This amount does not include 208,000 shares issuable upon exercise of options which are not exercisable within 60 days. Dr. Reininger was not a Named Executive Officer during the fiscal year ended December 31, 2012. However, Dr. Reininger is an executive officer and the Company anticipates that Dr. Reininger will be a Named Executive Officer for 2013.

(i) This amount includes 73,764 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 59,250 shares of unvested restricted stock.

(j) This amount includes 20,000 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 59,250 shares of unvested restricted stock.

(k) This amount includes 68,250 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 60,000 shares of unvested restricted stock and 378,750 shares issuable upon exercise of options which are not exercisable within 60 days.

(l) This amount includes 1,366,348 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 106,824 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 1,211,250 shares of unvested restricted stock and 2,022,416 shares issuable upon the exercise of options which are not exercisable within 60 days. The Company itself is the trustee of the Navidea Biopharmaceuticals, Inc. 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 661,461 shares of common stock. The 12 persons referenced in this disclosure include each director and named executive officer listed in the table.

(m) Based on information filed on Schedule 13G with the Securities and Exchange Commission as of December 31, 2012. 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 22,687,260 shares of common stock issuable upon conversion of 6,938 shares of Series B Convertible Preferred Stock, 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 X Warrant and the Series AA Warrant each provide that the holder of shares of the Preferred Stock, 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.

(n) Less than one percent.

(o) 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 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, and renewed again in August 2012. During 2012, we paid Dr. Rowinsky a total of $105,000 in cash consulting fees, and issued 13,764 options to purchase shares of common stock of the Company. In September 2012, 30,000 shares of restricted stock that were originally issued related to the August 2011 consulting agreement renewal vested as a result of the Company's commencement of the Phase 2 clinical study of its NAV4694 product candidate.

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 MKT Company Guide. Our Board of Directors has determined that Messrs. Ford and Troup, and Drs. Drake and Jones, meet the independence requirements.

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 2012 fiscal year, the audit of the Company's internal control over financial reporting as of December 31, 2012, the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2012 fiscal year, consents related to the Company's registration statements filed during the 2012 fiscal year, and consulting services related to certain debt and equity instruments during the 2012 fiscal year were $264,790 (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 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).

Audit-Related Fees. No fees were billed by BDO USA, LLP for audit-related services for the 2012 or 2011 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 2011 tax year during the 2012 fiscal year were $24,800 (including direct engagement expenses). 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).

All Other Fees. No fees were billed by BDO USA, LLP for services other than the audit, audit-related and tax services for the 2012 or 2011 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)(incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K filed March 7, 2012, and incorporated herein by reference).
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. Fourth Amended and Restated 2002 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement for the Company's 2012 Annual Meeting of Stockholders, filed July 10, 2012).
10.2	Form of Stock Option Agreement under the Navidea Biopharmaceuticals, Inc. Fourth 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 Fourth 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 Dr. Frederick O. Cope and Mr. Brent L. Larson. This agreement is one of two 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 Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 7, 2013).

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 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 7, 2013).

10.6	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).
10.7	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).
10.8	Employment Agreement, dated June 1 2012, 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 7, 2012).
10.9	Employment Agreement, effective November 1, 2012, between the Company and Cornelia Reininger, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 6, 2012).
10.10	Separation Agreement and Release, dated March 30, 2011, 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).
10.11	Consulting Agreement, dated March 30, 2011, 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).
10.12	Consulting Services Agreement, dated August 3, 2011, 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).
10.13	Consulting Services Agreement, dated August 27, 2012, 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 30, 2012).
10.14	Navidea Biopharmaceuticals, Inc. 2012 Cash Bonus Plan (incorporated by reference to the Company's Current Report on Form 8-K filed April 13, 2012).
10.15	Navidea Biopharmaceuticals, Inc. 2013 Cash Bonus Plan (incorporated by reference to the Company's Current Report on Form 8-K filed February 27, 2013).
10.16	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).
10.17	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).
10.18	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).
10.19	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).

10.20	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).
10.21	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).
10.22	Product Supply Agreement between the Company and TriVirix International, Inc., dated February 5, 2004 (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.17 to the Company's December 31, 2004 Form 10-KSB).
10.23	Supply and Distribution Agreement, dated November 15, 2007, 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).
10.24	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).
10.25	Sublicense Agreement, dated July 31, 2012, between Alseres Pharmaceuticals, 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 United States Securities and Exchange Commission)(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 6, 2012).
10.26	Registration Rights Agreement, dated July 31, 2012, between the Company and Alseres Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 6, 2012).
10.27	Securities Purchase Agreement, dated as of December 26, 2007, 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).
10.28	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).
10.29	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, 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).

10.30	Securities Amendment and Exchange Agreement, dated July 24, 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 July 29, 2009).
10.31	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).
10.32	Amendment to Series X Warrant, dated December 13, 2012, 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 19, 2012).
10.33	Wavier of Automatic Conversion of Series B Convertible Preferred Stock, dated December 13, 2012, by and among the Company, Platinum Montaur Life Sciences, LLC, and Platinum Partners Value Arbitrage Fund, L.P. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 19, 2012).
10.34	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).
10.35	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).
10.36	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).
10.37	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).
10.38	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).
10.39	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).
10.40	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).
10.41	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 Loan Agreement, dated July 25, 2012, 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 31, 2012).

10.43	Promissory Note, dated July 25, 2012, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 31, 2012).
10.44	Securities Exchange Agreement, dated November 27, 2012, between the Company and Platinum Partners Value Arbitrage Fund, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 3, 2012).
10.45	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).
10.46	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).
10.47	Underwriting Agreement, dated January 29, 2013, between the Company and Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 31, 2013).
10.48	Asset Purchase Agreement, dated May 24, 2011, 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).
10.49	License Agreement, dated December 9, 2011, 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/A filed April 11, 2012).
10.50	Loan and Security Agreement, dated December 29, 2011, 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).
10.51	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.*
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension Schema Document**
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document**
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document**
101.LAB	XBRL Taxonomy Extension Label Linkbase Document**
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document**

* Filed herewith.

** IN ACCORDANCE WITH THE TEMPORARY HARDSHIP EXEMPTION PROVIDED BY RULE 201 OF REGULATION S-T, THE DATE BY WHICH THE INTERACTIVE DATA FILE IS REQUIRED TO BE SUBMITTED HAS BEEN EXTENDED BY SIX BUSINESS DAYS.

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 18, 2013

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)	March 18, 2013
/s/ Brent L. Larson* Brent L. Larson	Senior Vice President and Chief Financial Officer (principal financial officer)	March 18, 2013
/s/ Gordon A. Troup* Gordon A. Troup	Chairman, Director	March 18, 2013
/s/ Peter F. Drake* Peter F. Drake	Director	March 18, 2013
/s/ Brendan A. Ford* Brendan A. Ford	Director	March 18, 2013

/s/ Jess Emery Jones* Jess Emery Jones	Director	March 18, 2013
/s/ Eric K. Rowinsky* Eric K. Rowinsky	Director	March 18, 2013

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

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

NAVIDEA BIOPHARMACEUTICALS, INC.

FORM 10-K ANNUAL REPORT

As of December 31, 2012 and 2011

and for Each of the

Three Years in the Period Ended

December 31, 2012

FINANCIAL STATEMENTS

NAVIDEA BIOPHARMACEUTICALS, INC. and SUBSIDIARIES

Index to Financial Statements

Consolidated Financial Statements of Navidea Biopharmaceuticals, Inc.

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. as of December 31, 2012 and 2011 and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the results of its operations and cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, 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 18, 2013 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Chicago, Illinois

March 18, 2013

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Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets

ASSETS	December 31, 2012	December 31, 2011
Current assets:		
Cash	$ 9,118,564	$ 28,644,004
Accounts receivable	17,605	15,794
Inventory	297,500	821,549
Prepaid expenses and other	1,183,714	565,174
Total current assets	10,617,383	30,046,521
Property and equipment	2,026,895	1,441,229
Less accumulated depreciation and amortization	1,092,317	977,960
	934,578	463,269
Patents and trademarks	115,053	106,592
Less accumulated amortization	22,571	21,171
	92,482	85,421
Deferred debt issuance costs and other	327,954	598,709
Total assets	$ 11,972,397	$ 31,193,920

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets, continued

LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	December 31, 2012	December 31, 2011
Current liabilities:		
Accounts payable	$1,417,463	$681,754
Accrued liabilities and other	2,016,358	2,097,786
Notes payable, current, net of discount of $202,287	2,756,718	—
Derivative liabilities	—	568,930
Total current liabilities	6,190,539	3,348,470
Notes payable, net of discounts of $93,038 and $543,612, respectively	6,930,112	6,456,388
Other liabilities	257,122	257,315
Total liabilities	13,377,773	10,062,173
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 6,938 and 9,083 Series B shares, and 0 and 1,000 Series C shares, issued and outstanding at December 31, 2012 and 2011, respectively	7	10
Common stock; $.001 par value; 200,000,000 shares authorized; 113,018,772 and 95,398,961 shares issued and outstanding at December 31, 2012 and 2011, respectively	113,019	95,399
Additional paid-in capital	273,039,442	266,393,645
Accumulated deficit	(274,557,844)	(245,357,307)
Total stockholders' (deficit) equity	(1,405,376)	21,131,747
Total liabilities and stockholders' (deficit) equity	$11,972,397	$31,193,920

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

	Years Ended December 31,		
	2012	2011	2010
Revenue	$78,738	$597,729	$617,392
Operating expenses:			
Research and development	16,890,482	15,154,365	8,941,046
Selling, general and administrative	11,177,559	9,547,779	4,353,136
Total operating expenses	28,068,041	24,702,144	13,294,182
Loss from operations	(27,989,303)	(24,104,415)	(12,676,790)
Other income (expense):			
Interest income	25,044	25,755	8,804
Interest expense	(1,166,332)	(13,330)	(554,988)
Change in derivative liabilities	32,110	(952,375)	(1,336,234)
Loss on extinguishment of debt	—	—	(41,717,380)
Other	(58,723)	(3,211)	32,594
Total other expense, net	(1,167,901)	(943,161)	(43,567,204)
Loss before income taxes	(29,157,204)	(25,047,576)	(56,243,994)
Benefit from income taxes	—	7,880,143	2,134,903
Loss from continuing operations	(29,157,204)	(17,167,433)	(54,109,091)
Discontinued operations, net of tax effect:			
Gain on sale – GDS Business	—	19,450,891	—
Income from operations	—	3,329,534	4,144,223
Net (loss) income	(29,157,204)	5,612,992	(49,964,868)
Preferred stock dividends	(43,333)	(100,000)	(8,206,745)
Net (loss) income attributable to common stockholders	$(29,200,537)	$5,512,992	$(58,171,613)
(Loss) income per common share (basic and diluted):			
Continuing operations	$(0.29)	$(0.17)	$(0.77)
Discontinued operations	$—	$0.23	$0.05
Attributable to common stockholders	$(0.29)	$0.06	$(0.72)
Weighted average shares outstanding:			

Basic and diluted	99,059,997	90,509,326	80,726,498

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Stockholders' Equity (Deficit)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
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 stock options, net	—	—	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
	—	—	—	—	597,672	—	597,672

Stock compensation expense							
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
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	—	—	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
Issued restricted stock	—	—	455,000	455	—	—	455
Cancelled restricted stock	—	—	(600,500)	(601)	5	—	(596)
Issued stock upon exercise of stock options, net	—	—	1,225,271	1,226	742,069	—	743,295
Cancelled stock upon repurchase from executives	—	—	(37,500)	(37)	(100,838)	—	(100,875)
Issued stock to 401(k) plan	—	—	17,390	17	50,255	—	50,272
Issued stock upon exercise of warrants,	—	—	6,020,000	6,020	1,972,581	—	1,978,601

net							
Conversion of Series B preferred stock to common stock, net	(2,145)	(2)	7,014,150	7,014	(7,012)	—	—
Conversion of Series C preferred stock to common stock	(1,000)	(1)	3,226,000	3,226	(3,225)	—	—
Issued stock for payment of sublicense fee	—	—	300,000	300	1,145,700	—	1,146,000
Effect of change in terms of warrants	—	—	—	—	496,671	—	496,671
Short-swing profit returned to the Company	—	—	—	—	45,473	—	45,473
Stock compensation expense	—	—	—	—	2,304,118	—	2,304,118
Preferred stock dividends	—	—	—	—	—	(43,333)	(43,333)
Net loss	—	—	—	—	—	(29,157,204)	(29,157,204)
Balance, December 31, 2012	6,938	$ 7	113,018,772	$113,019	$273,039,442	$(274,557,844)	$(1,405,376)

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2012	2011	2010
Cash flows from operating activities:			
Net (loss) income	$(29,157,204)	$5,612,992	$(49,964,868)
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Depreciation and amortization of equipment	198,822	175,296	215,462
Amortization of intangible assets	1,400	1,248	7,998
Loss on disposal and abandonment of assets	2,534	18,645	7,476
Amortization of debt discount and debt offering costs	544,517	3,805	16,109
Issuance of common stock in payment of interest and dividends	—	—	476,667
Stock compensation expense	2,304,118	3,592,090	597,672
Change in derivative liabilities	(32,110)	952,375	1,336,234
Loss on extinguishment of debt	—	—	41,717,380
Issuance of warrants in connection with consulting agreement	—	—	279,367
Gain on sale of GDS Business, before income tax	—	(26,173,805)	—
Issuance of common stock for payment of sublicense fee	1,146,000	—	—
Other	61,928	61,971	40,623
Change in operating assets and liabilities:			
Accounts receivable	6,499	(219,021)	(707,914)
Inventory	524,049	(53,289)	(381,382)
Prepaid expenses and other assets	(385,125)	(40,204)	39,232
Accounts payable	736,109	(538,666)	759,411
Accrued liabilities and other liabilities	125,144	487,055	157,899
Deferred revenue	—	109,503	232,866
Net cash used in operating activities	(23,923,319)	(16,010,005)	(5,169,768)
Cash flows from investing activities:			
Purchases of equipment	(663,348)	(183,830)	(366,629)
Proceeds from sales of equipment	—	1,000	—
Proceeds from sale of GDS Business	—	30,159,527	—
Payments of costs to sell GDS Business	—	(2,765,932)	—
Patent and trademark costs	(8,460)	(52,504)	(32,111)
Net cash (used in) provided by investing activities	(671,808)	27,158,261	(398,740)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	2,724,189	7,198,373	7,092,163
Payment for common stock repurchased from executives	(100,875)	—	—
Payment of tax withholdings related to stock-based compensation	(8,765)	(2,762,710)	(133,153)
Payment of stock issuance costs	—	—	(478,111)
Payment of preferred stock dividends	(100,000)	(100,000)	(111,389)
Proceeds from notes payable	4,000,000	7,000,000	—

Payment of debt issuance costs	(153,949)	(189,390)	—
Principal payments on notes payable	(1,285,046)	(62,411)	(8,710)
Payments under capital leases	(5,867)	(8,620)	(11,628)
Net cash provided by financing activities	5,069,687	11,075,242	6,349,172
Net (decrease) increase in cash	(19,525,440)	22,223,498	780,664
Cash, beginning of year	28,644,004	6,420,506	5,639,842
Cash, end of year	$9,118,564	$28,644,004	$6,420,506

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. (Navidea, the Company, or we), a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Lymphoseek® (technetium Tc 99m tilmanocept) Injection, is a novel, receptor-targeted, small-molecule, investigational radiopharmaceutical used in lymphatic mapping procedures that are performed to help stage breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. As discussed in Note 20(a), Subsequent Events, Lymphoseek was approved by the FDA on March 13, 2013. In addition, we are currently developing three other radiopharmaceutical agent platforms. The first, NAV4694, is an F-18 radiolabeled positron emission tomography (PET) imaging agent being developed as an aid in the diagnosis of patients with signs or symptoms of cognitive impairment such as Alzheimer's disease (AD). The second, NAV5001 (E-IACFT), is an Iodine-123 radiolabeled single photon emission computed tomography (SPECT) imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders, with potential use as a diagnostic aid in dementia. The third, RIGScan™, is a radiolabeled monoclonal antibody being developed as a diagnostic aid for use during surgery to help surgeons locate occult or metastatic cancer, with a primary focus on colorectal cancer. These drug products are still in development and must be cleared for marketing by the appropriate regulatory authorities 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 in Note 2, 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% of net sales were made to Devicor or EES for the years ended December 31, 2011 and 2010.

In 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 was formed to combine 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. However, ACT is no longer under active development by Navidea.

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.

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.

Notes to the Consolidated Financial Statements

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) Notes payable: The carrying value of our debt at December 31, 2012 is presented as the face amount of the notes less unamortized discounts. The estimated fair value of our debt was calculated using a discounted cash flow analysis, which includes Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. At December 31, 2012, the fair value of our notes payable is approximately $9.7 million, which approximates face value. See Note 11.

(3) 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 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 12.

e. **Stock-Based Compensation:** At December 31, 2012, we have instruments outstanding under two stock-based compensation plans; the 1996 Stock Incentive Plan (the 1996 Plan) and the Fourth 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 12 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.

Notes to the Consolidated Financial Statements

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 the fair value of stock option awards for the years ended December 31, 2012, 2011 and 2010 are noted in the following table:

	2012	2011	2010
Expected volatility	63%-72%	64%-71%	61%-68%
Weighted-average volatility	65%	69%	66%
Expected dividends	—	—	—
Expected term (in years)	5.0-6.3	5.3-6.3	6.0-6.3
Risk-free rate	0.6%-1.2%	1.3%-2.4%	1.7%-2.4%

Compensation cost arising from stock-based awards is recognized as expense over either (1) the requisite service period or (2) the estimated performance period. The restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award. Restricted stock may vest based on the passage of time, or they may vest upon occurrence of a specific event or achievement of goals as defined in the grant agreements. In such cases, 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, 2012 or 2011.

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 products 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, slower than expected sales, 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. We estimate a reserve for obsolete inventory based on management's judgment of probable future

commercial use, which is based on an analysis of current inventory levels, historical and estimated future sales and production rates, and estimated shelf lives. As discussed in Note 20(a), Subsequent Events, Lymphoseek was approved by the FDA on March 13, 2013. See Note 6.

h. **Property and Equipment:** Property and equipment are stated at cost, less accumulated depreciation and amortization. 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.

Notes to the Consolidated Financial Statements

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 Note 7.

k. **Deferred Debt Issuance Costs:** We defer costs associated with the issuance of notes payable and amortize those costs over the period of the notes using the effective interest method. In 2011, we incurred $593,000 of debt issuance costs related to notes payable. During 2012, 2011 and 2010, we recorded amortization of $296,000, $2,000 and $4,000, respectively, of deferred debt issuance costs. Other assets at December 31, 2012 and 2011 include net deferred debt issuance costs of $295,000 and $591,000, respectively. See Note 11.

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 12.

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. We also recognize revenue from the reimbursement by our partners of certain expenditures for which the Company has principal responsibility.

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, 2012 and 2011.

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. See Note 14.

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, 2012 or 2011 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, 2012, tax years 2009-2012 remained subject to examination by federal and state tax authorities.

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 was effective for interim and annual reporting periods beginning after December 15, 2011 and was applied prospectively. ASU 2011-04 did not have a material effect on our consolidated financial statements.

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2. Discontinued Operations

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. 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.

During 2011 and 2010, we wrote off $1,000 and $65,000, 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 and 2010, we recognized license revenue of $63,000 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

We reclassified revenues and expenses related 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, have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

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

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.

3. Fair Value Hierarchy

There were no financial assets or liabilities measured at fair value on a recurring basis as of December 31, 2012. The following table sets forth, by level, financial liabilities measured at fair value on a recurring basis as of December 31, 2011:

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

	Quoted Prices in Active Markets for	Significant Other Observable	Significant Unobservable Inputs	Balance as of December 31,

Description	Identical Assets and Liabilities (Level 1)	Inputs (Level 2)	(Level 3)	2011
Liabilities:				
Derivative liabilities related to warrants, current	$ —	$ 568,930	$ —	$ 568,930

There were no Level 1 liabilities outstanding at any time during the years ended December 31, 2012 and 2011. A total of $484,419 and $1,978,818 of our Level 2 liabilities were reclassified to equity related to modifying certain outstanding warrants to remove the language that had previously required them to be classified as derivative liabilities during the years ended December 31, 2012 and 2011.

There were no Level 3 liabilities outstanding at any time during the years ended December 31, 2012 or 2011.

Notes to the Consolidated Financial Statements

4. Stock-Based Compensation

For the years ended December 31, 2012, 2011 and 2010, our total stock-based compensation expense was approximately $2.3 million, $3.6 million and $598,000, respectively. We have not recorded any income tax benefit related to stock-based compensation for the years ended December 31, 2012, 2011 and 2010.

A summary of the status of our stock options as of December 31, 2012, and changes during the year then ended, is presented below:

	Year Ended December 31, 2012			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of year	3,315,000	$ 1.02		
Granted	1,351,027	3.16		
Exercised	(1,232,001)	0.62		
Forfeited	(12,249)	2.18		
Expired	(9,000)	1.73		
Outstanding at end of year	3,412,777	$ 2.01	6.8 years	$3,530,862
Exercisable at end of year	1,836,237	$ 1.10	4.9 years	$3,271,747

The weighted average grant-date fair value of options granted in 2012, 2011 and 2010 was $1.86, $2.22 and $1.13, respectively. During 2012, 1,232,001 stock options with an aggregate intrinsic value of $3,360,686 were exercised in exchange for issuance of 1,225,270 shares of our common stock, resulting in gross proceeds of $752,060. 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 2012, 2011 and 2010, we paid tax withholdings related to stock options exercised of $9,000, $2.8 million and $133,000, respectively. During 2012, 2011 and 2010, the aggregate fair value of stock options vested was $460,000, $998,000 and $379,000, respectively.

A summary of the status of our unvested restricted stock as of December 31, 2012, and changes during the year then ended, is presented below:

	Year Ended December 31, 2012	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of year	1,556,000	$ 2.48
Granted	405,000	3.14
Vested	(30,000)	2.86
Forfeited	—	—
Expired	(596,000)	3.36
Unvested at end of year	1,335,000	$ 2.28

During 2012 and 2011, 30,000 and 1,050,000 shares, respectively, of restricted stock vested with aggregate fair values of $85,000 and $4.2 million, respectively. No restricted stock vested during 2010.

Notes to the Consolidated Financial Statements

As of December 31, 2012, there was approximately $2.2 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 2.0 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 calculation of basic and diluted earnings (loss) per share for the years ended December 31, 2012, 2011 and 2010:

	Years Ended December 31,		
	2012	2011	2010
Net (loss) income	$(29,157,204)	$5,612,992	$(49,964,868)
Preferred stock dividends	(43,333)	(100,000)	(8,206,745)
Net (loss) income attributable to common stockholders	$(29,200,537)	$5,512,992	$(58,171,613)
Weighted average shares outstanding (basic and diluted)	99,059,997	90,509,326	80,726,498
(Loss) income per common share (basic and diluted)	$(0.29)	$0.06	$(0.72)

Earnings (loss) per common share for the years ended December 31, 2012, 2011 and 2010 excludes the effects of 38.4 million, 55.7 million and 64.1 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 required to be included in the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, 1,335,000, 1,556,000 and 2,374,500 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the years ended December 31, 2012, 2011 and 2010, respectively,

because such inclusion would be anti-dilutive.

6. Inventory

The components of net inventory at December 31, 2012 and 2011 are as follows:

	2012	2011
Pharmaceutical materials	$297,500	$482,000
Pharmaceutical work-in-process	—	339,549
	$297,500	$821,549

During 2012 and 2011, we capitalized $525,000 and $213,000, respectively, of inventory costs associated with our Lymphoseek product. During 2012, we wrote off $741,000 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

We estimate a reserve for obsolete inventory based on management's judgment of probable future commercial use, which is based on an analysis of current inventory levels, historical and estimated future sales and production rates, and estimated shelf lives. During 2012, we recorded an obsolescence reserve for $308,000 of Lymphoseek inventory based on delays in U.S. regulatory approval impacting the timing of future commercial use of the specific lots previously capitalized.

7. Property and Equipment

The major classes of property and equipment are as follows:

	Useful Life	2012	2011
Production machinery and equipment	5 years	$397,643	$218,205
Other machinery and equipment, primarily computers and research equipment	3 – 5 years	581,409	399,587
Furniture and fixtures	7 years	439,716	416,005
Software	3 years	471,811	305,282
Leasehold improvements	Life of Lease[1]	136,316	102,150
		$2,026,895	$1,441,229

[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 $30,000 and $20,000 of equipment under capital leases with accumulated amortization of $16,000 and $11,000 at December 31, 2012 and 2011, respectively. During 2012, 2011 and 2010, we recorded $199,000, $117,000 and $102,000, respectively, of depreciation and amortization related to property and equipment.

8. Accrued Liabilities and Other

Accrued liabilities and other at December 31, 2012 and 2011 consist of the following:

	2012	2011
Contracted services	$1,183,805	$969,150
Compensation	762,266	953,641
Other	70,287	174,995
	$2,016,358	$2,097,786

9. Separation of Former CEO

In March 2011, Navidea announced the departure of our then-current President and CEO, David C. Bupp, effective April 15, 2011. The following table summarizes accrued expenses as of December 31, 2012 and 2011, including employer payroll tax obligations, related to the provisions of Mr. Bupp's separation agreement:

	As of December 31,	
	2012	2011
Separation	$—	$180,074
Pro-rated 2011 bonus	—	60,870
Estimated cost of continuing healthcare coverage	24,747	61,875
	$24,747	$302,819

Notes to the Consolidated Financial Statements

10. Convertible Securities

In June 2010, we entered into a Securities Exchange Agreement with Platinum Montaur Life Sciences, LLC (Montaur), pursuant to which Montaur exchanged their 10% Series A Convertible Senior Secured Promissory Note with an outstanding principal amount of $7,000,000, their 10% Series B Convertible Senior Secured Promissory Note with an outstanding principal amount of $3,000,000, and their 3,000 shares of 8% Series A Cumulative Convertible 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 and carries no dividend requirement. In the event of the liquidation of the Company, the holders of shares of the Series B Preferred Stock have preference over the common stock. After payment of the full liquidation preference amount to which each holder is entitled, such holders of shares of Series B Preferred Stock will not be entitled to any further participation as such in any distribution of the assets of the Company. 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 David C. Bupp, then our President and CEO, and certain members of his family (the Bupp Investors), pursuant to which the Bupp Investors exchanged their 10% Convertible Secured Promissory Note with an outstanding principal amount of $1,000,000 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 had a 10% dividend rate and participated equally with our common stock in liquidation proceeds based upon the number of common shares into which the Series C Preferred Stock was convertible. The exchange of the Montaur Notes, the Series A Preferred Stock and the 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 May 2011, Montaur converted 917 shares of their Series B Preferred Stock into 2,998,590 shares of our common stock under the terms of the Series B Preferred Stock. In July 2012, Montaur converted 3,063 shares of their Series B Preferred Stock into 10,016,010 shares of our common stock under the terms of the Series B Preferred Stock. In November 2012, we entered into a Securities Exchange Agreement with Platinum Partners Value Arbitrage Fund, L.P. (Platinum), an affiliate of Montaur, pursuant to which Platinum exchanged 3,001,860 shares of our common stock owned by Platinum for 918 shares of our Series B Preferred Stock. As of December 31, 2012, there are 6,938 shares of Series B Preferred Stock outstanding which are convertible into 22,687,260 shares of our common stock.

In December 2012, we entered into a Waiver Agreement (the Waiver) pursuant to which Montaur and Platinum, as the sole holders of the Series B Preferred Stock, agreed to irrevocably waive the provisions set forth in the certificate of designations for the Series B Preferred Stock (the Certificate) which provided that all outstanding shares of Series B

Preferred Stock would automatically convert into shares of common stock on December 31, 2012. The Waiver will remain in effect until December 31, 2013, upon which date all outstanding shares of Series B Preferred Stock will automatically convert into common stock pursuant to the terms of the Certificate. In addition, we amended the terms of Montaur's Series X warrant to extend the expiration date from April 16, 2013 to December 31, 2013. Also in December 2012, the Series C Preferred Stock held by the Bupp Investors automatically converted into 3,226,000 shares of our common stock under the terms of the Series C Preferred Stock.

During the year ended December 31, 2010, we recorded interest expense of $16,000 related to amortization of the debt discounts and deferred financing costs related to our convertible securities.

Notes to the Consolidated Financial Statements

11. Notes Payable

In December 2011, we executed a Loan and Security Agreement (the Loan Agreement) with Hercules Technology II, L.P. (Hercules), providing for a maximum borrowing of $10 million by the Company in two advances. 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, 2012 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, the Loan Agreement provided Navidea with the option to draw a second advance in the principal amount of $3,000,000 if certain conditions were met by June 30, 2012. Such conditions were not met and Hercules no longer has an obligation to provide the additional $3,000,000. The Loan Agreement provided for an interest-only period beginning on December 29, 2011 and expiring on July 1, 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. As such, a portion of the principal, net of related discounts, has been classified as a current liability as of December 31, 2012. The outstanding balance of the debt is due December 1, 2014. 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, 2012, 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 remained in effect for the first 365 days the warrant was 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 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 are being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement.

During 2012, we paid $1.3 million of principal payments on our note payable to Hercules. As of December 31, 2012, the remaining outstanding principal balance of the Hercules debt was approximately $5.7 million. During the years ended December 31, 2012 and 2011, we recorded interest expense of $545,000 and $4,000, respectively, related to amortization of the debt discounts and deferred financing costs related to our convertible notes.

In July 2012, we entered into an agreement with Montaur to provide us with a credit facility of up to $50 million. Under the terms of the agreement, Montaur committed to extend up to $15 million in debt, which is available immediately, to the Company at an interest rate equal to the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10.0%; or (c) the highest rate of interest then payable pursuant to the Hercules Loan Agreement plus 0.125% (effective interest rate at December 31, 2012 was 10.125%). Montaur has committed an additional $20 million upon FDA approval of Lymphoseek on consistent terms, with another $15 million potentially available on terms to be negotiated. As discussed in Note 20(a), Subsequent Events, Lymphoseek was approved by the FDA on March 13, 2013. Principal amounts are due the earlier of two years from the date of draw or June 30, 2016. No conversion features or warrants are associated with the facility.

During 2012, we drew a total of $4.0 million under the credit facility and recorded interest expense of $15,000. As of December 31, 2012, the total principal amount due under the credit facility was $4.0 million.

Annual principal maturities of our notes payable are $2.7 million and $7.0 million in 2013 and 2014, respectively.

Notes to the Consolidated Financial Statements

12. Derivative Instruments

Certain embedded features of our convertible securities and notes payable, as well as warrants to purchase our common stock, are treated as derivative liabilities. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.

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. 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 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.

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.

Notes to the Consolidated Financial Statements

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 remained in effect for the first 365 days the warrant was 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 net effect of marking the Series GG warrants to market during 2012 resulted in net decreases in the estimated fair value of the derivative liability of $38,000, which were recorded as non-cash income. In December 2012, the provisions of the Series GG warrant that resulted in treatment of the instrument as a derivative liability expired. As a result of the expiration of such provisions of the Series GG warrant, we reclassified $484,000 in derivative liabilities related to those warrants to additional paid-in capital. See Note 11.

During 2012, the holder of 20,000 Series V warrants exercised them in exchange for issuance of 20,000 shares of our common stock, resulting in gross proceeds of $6,200. As a result of the Series V warrant exercise, we reclassified $52,000 in derivative liabilities related to those warrants to additional paid-in capital.

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, 2012, 2011 and 2010 resulted in net (decreases) increases in non-cash (income) expense of ($32,000), $952,000 and $1.3 million. The total estimated fair value of our derivative liabilities was $569,000 and $2.5 million as of December 31, 2011 and 2010, respectively. No derivative liabilities were outstanding as of December 31, 2012.

13. 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, 2012, there are 11.5 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from $0.46 to $2.375 per share with a weighted average exercise price per share of $0.68.

The following table summarizes information about our outstanding warrants at December 31, 2012:

	Exercise Price	Number of Warrants	Expiration Date
Series X	$ 0.46	8,333,333	December 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
	$ 0.68	11,530,877	

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.

Notes to the Consolidated Financial Statements

During 2012, Montaur exercised 6,000,000 Series W warrants in exchange for issuance of 6,000,000 shares of our common stock, resulting in gross proceeds of $1,920,000.

See Note 12 for a discussion of Series V, Series Z, Series CC, and Series DD warrant transactions during 2012.

c. **Common Stock Reserved:** As of December 31, 2012, we have reserved 38,713,946 shares of authorized common stock for the exercise of all outstanding options, warrants, convertible preferred stock and convertible debt.

14. Income Taxes

As of December 31, 2012 and 2011, our deferred tax assets were approximately $33.7 million and $37.7 million, respectively. The components of our deferred tax assets are summarized as follows:

	As of December 31,	
	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	$24,767,569	$29,701,483
R&D credit carryforwards	6,546,049	7,610,672
Temporary differences	2,408,108	371,610
Deferred tax assets before valuation allowance	33,721,726	37,683,765
Valuation allowance	(33,721,726)	(37,683,765)
Net deferred tax assets	$—	$—

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, 2012 and 2011.

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, 2012.

As of December 31, 2012 and 2011, we had U.S. net operating loss carryforwards of approximately $80.9 million and $74.1 million, respectively. Of that amount, $14.1 million and $9.1 million relates to stock-based compensation tax deductions in excess of book compensation expense (APIC NOLs) as of December 31, 2012 and 2011, respectively, 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, 2012 and 2011, we had U.S. R&D credit carryforwards of approximately $6.5 million and $7.6 million, respectively.

Notes to the Consolidated Financial Statements

U.S. net operating loss carryforwards of $20.8 million and $16.6 million and R&D credit carryforwards of $1.1 million and $346,000 expired during 2012 and 2011, 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, 2012	
Generated	Expiration	U.S. Net Operating Loss Carryforwards	U.S. R&D Credit Carryforwards
1998	2013	$17,142,781	$ 1,173,387
1999	2014	—	130,359
2000	2015	—	71,713
2001	2016	—	39,128
2002	2017	1,282,447	5,350
2003	2018	337,714	2,905
2004	2019	1,237,146	22,861
2005	2020	3,246,062	218,332
2006	2021	3,127,238	365,541
2007	2022	2,863,443	342,898
2008	2023	2,826,656	531,539
2009	2024	13,753,769	596,843
2010	2025	5,425,105	1,094,449
2011	2026	1,904,744	1,950,744
2012	2027	27,744,687	—
Total carryforwards		$80,891,792	$ 6,546,049

The American Taxpayer Relief Act of 2012 (the Act) cleared the House of Representatives and the Senate on January 2, 2013 and was signed into law by President Obama on January 2, 2013. The credit for certain research and experimentation expenses expired at the end of 2011. The act retroactively extends the credit through the end of 2013. Under current accounting guidelines, the effects of new legislation are recognized upon enactment and as such the Company has not included a 2012 R&D tax credit in the above table.

During the years ended December 31, 2012, 2011 and 2010, Cardiosonix recorded losses for financial reporting purposes of $14,000, $19,000 and $15,000, respectively. As of December 31, 2012 and 2011, 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, 2012 and 2011.

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 2010, we completed a Section 382 study and concluded that a Section 382 ownership change has not occurred. Based on changes in the Company's ownership in 2011 and 2012, we do not believe a Section 382 ownership change has occurred in such years that would impact utilization of the Company's net operating loss and R&D tax credit carryforwards.

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

	Years Ended December 31,					
	2012		2011		2010	
	Amount	%	Amount	%	Amount	%
Benefit at statutory rate	$(9,913,450)	(34.0)%	$(8,516,176)	(34.0)%	$(19,122,958)	(34.0)%
Adjustments to valuation allowance	9,668,770	33.2 %	—	—	3,410,056	6.1 %
Loss on extinguishment of debt	—	—	—	—	14,179,468	25.2 %
Permanent items and other	244,680	0.8 %	636,033	2.5 %	(601,469)	(1.1)%
Benefit per financial statements	$—		$(7,880,143)		$(2,134,903)	

Notes to the Consolidated Financial Statements

15. 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 Lymphoseek drug substance. 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 $939,000, $544,000 and $1.0 million for the years ended December 31, 2012, 2011 and 2010. As of December 31, 2012, we have issued purchase orders under the agreement with Reliable for $119,000 of our products for delivery through December 2013.

b. **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 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 $33,000, $98,000 and $36,000 in 2012, 2011 and 2010, respectively, and were recorded in research and development expenses.

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 $31,000, $28,000 and $27,000 in 2012, 2011 and 2010, respectively, and were recorded in research and development expenses.

In December 2011, we executed a license agreement with AstraZeneca AB for NAV694, 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 NAV4694 or the expiration of the underlying patents. Under the terms of the license agreement, AstraZeneca granted us an exclusive worldwide royalty-bearing license for NAV4694 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 $14,000 and $5.0 million in 2012 and 2011, respectively, and were recorded in research and development expenses.

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In July 2012, we entered into an agreement with Alseres Pharmaceuticals, Inc. (Alseres) to sublicense NAV5001, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders, with a potential use as a diagnostic aid in dementia. Under the terms of the sublicense agreement, Alseres granted Navidea an exclusive, worldwide sublicense to research, develop and commercialize NAV5001. The terms of the agreement required Navidea to make a one-time sublicense execution payment to Alseres equal to (i) $175,000 in cash and (ii) 300,000 shares of our common stock. The sublicense agreement also provides for contingent milestone payments of up to $2.9 million, $2.5 million of which will principally occur at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.15 million shares of Navidea common stock, 950,000 shares of which are issuable at the time of product registration or upon commercial sales. In addition, the sublicense terms anticipate royalties on annual net sales of the approved product which are consistent with industry-standard terms and certain sublicense extension fees, payable in cash and shares of common stock, in the event certain diligence milestones are not met. Total costs related to the Alseres sublicense agreement were $1.8 million in 2012, 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 2012, we have paid the OCS a total of $82,000 in royalties related to sales of products developed under this program. As of December 31, 2012, we have accrued obligations for royalties totaling $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. The license agreement with OSU was terminated effective December 31, 2012. Total costs related to the OSU license agreement were $100,000 in 2012, and were recorded in research and development expenses.

Notes to the Consolidated Financial Statements

c. **Employment Agreements:** We maintain employment agreements with seven 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, 2012, our maximum contingent liability under these agreements in such an event is approximately $3.1 million. The employment agreements also provide for severance, disability and death benefits.

16. Leases

We lease certain office equipment under capital leases which expire in 2013 and 2016. We also lease office space in Ohio under an operating lease that expires in October 2013 and office space in Massachusetts under an operating lease that expires in March 2014.

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

	Capital Leases	Operating Leases
2013	$8,789	$196,068
2014	3,039	19,105
2015	3,039	—
2016	2,532	—
	17,399	$215,173
Less amount representing interest	3,021	
Present value of net minimum lease payments	14,378	
Less current portion	7,276	
Capital lease obligations, excluding current portion	$7,102	

Total rental expense was $211,000, $154,000 and $125,000 for the years ended December 31, 2012, 2011 and 2010, respectively.

17. 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 $71,000, $56,000 and $37,000 during 2012, 2011 and 2010, respectively.

18. Supplemental Disclosure for Statements of Cash Flows

During 2012, 2011 and 2010, we paid interest aggregating $647,000, $4,000 and $136,000, respectively. During 2012, we issued 300,000 shares of our common stock as partial payment for the execution of a sublicense agreement. During 2010, we issued 347,832 shares of our common stock as payment of interest on our convertible debt and dividends on our convertible preferred stock. During 2012, 2011 and 2010, we issued 17,390, 35,233 and 53,499 shares of our common stock, respectively, as matching contributions to our 401(k) Plan. During 2011 and 2010, we transferred $25,000 and $79,000, respectively, of GDS Business inventory to fixed assets related to the creation and maintenance of a pool of service loaner equipment. During 2012 and 2010, we prepaid $267,000 and $71,000, respectively, of insurance premiums through the issuance of notes payable to finance companies with interest rates of 2.8% and 7.0%, respectively. During 2012, we purchased equipment under a capital lease totaling $9,000. During 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 13(a). Also during 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.

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19. 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.

20. Subsequent Events

a. **FDA Approval of Lymphoseek:** On March 13, 2013, the Company received FDA approval to market Lymphoseek. As a result of the Lymphoseek approval, 510,000 shares of restricted stock vested with an aggregate fair value of $1.6 million. The approval of Lymphoseek also made an additional $20 million available to the Company under the credit facility with Montaur.

b. **Public Offering of Common Stock:** In January 2013, Navidea entered into an underwriting agreement with Ladenburg Thalmann & Co. Inc., related to a public offering of 1,542,389 shares of the Company's common stock at a price of $3.10 per share less underwriting discounts and commissions (the Offering). The Offering closed in February 2013, following the satisfaction of customary closing conditions. The net proceeds to the Company were approximately $4.4 million after deducting expenses associated with the Offering. The Company will use the net proceeds from the offering to fund the clinical development and launch of its current drug products, to fund other potential product pipeline opportunities, and for general corporate purposes. The Offering was made pursuant to the Company's existing effective shelf registration statement on Form S-3.

c. **Warrant Exercise:** In March 2013, Montaur exercised 3,000,000 of the Series X warrants in exchange for issuance of 3,000,000 shares of our common stock, resulting in gross proceeds of $1,380,000.