NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-K
March 14, 2014

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

FORM 10-K

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

For the fiscal year ended December 31, 2013

or

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

For the transition period from to to

Commission file number 001-35076

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.)
5600 Blazer Parkway, Suite 200, Dublin, Ohio (Address of principal executive offices)	43017-7550 (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 (Title of Class)	NYSE MKT (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 ý

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 ý

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 ý 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 ý 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. ¨

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

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

The aggregate market value of shares of common stock held by non-affiliates of the registrant on June 30, 2013 was $315,338,908.

The number of shares of common stock outstanding on February 28, 2014 was 149,702,543.

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 products and programs include:

- Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help evaluate patients with 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. It was approved by the U.S. Food and Drug Administration (FDA) in March 2013, and launched commercially in the United States in May 2013.
- Navidea's Manocept™ platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. This flexible and versatile platform acts as an engine for the design of purpose-built molecules offering the potential to be utilized across a range of diagnostic modalities, including single photon emission

computed tomography (SPECT), positron emission tomography (PET), intra-operative and/or optical-fluorescence detection in a variety of disease states.

- NAV4694 is a Fluorine-18 (F-18) radiolabeled PET imaging agent being developed as an aid in the diagnosis of patients with signs or symptoms of Alzheimer's disease (AD) and mild cognitive impairment (MCI).
- NAV5001 is an Iodine-123 (I-123) radiolabeled SPECT imaging agent being developed as an aid in the diagnosis of Parkinson's disease (PD) and other movement disorders, with potential use as a diagnostic aid in dementia.
- NAV1800 (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, and from July 2010 through August 2011 through a distribution arrangement with Devicor Medical Products, Inc. (Devicor).

We executed an Asset Purchase Agreement (APA) for the sale of the GDS Business (the Asset Sale) 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. To date, we have not received any such royalty payments.

Our Technology and Product Candidates

We focus on precision diagnostics technology, particularly in the area of radiopharmaceuticals. Innovative precision diagnostic agents hold the potential to improve diagnostic accuracy, clinical decision-making and patient care. Navidea's pipeline includes our commercial product, clinical-stage radiopharmaceutical agents, and a platform technology, all 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

In 2001, we entered 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. 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 in March 2013. Additional trials, one in head and neck cancer (NEO3-06) which is the focus of a supplemental New Drug Application (sNDA) that

now has a Prescription Drug User Fee Act (PDUFA) target date of June 16, 2014, an ongoing trial in colorectal cancer, and other planned investigator-sponsored trials, are anticipated to provide additional support for the potential expansion of Lymphoseek utilization into multiple other cancer types. A second sNDA aimed at expanding the Lymphoseek label to support more flexible utilization practices for Lymphoseek in lymphatic mapping and lymphoscintigraphy imaging has a PDUFA target date of October 16, 2014.

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 (WBCs) – from tissues into the bloodstream. The key components of the lymph system are lymph nodes – small anatomic structures that contain disease-fighting WBCs, 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, intraoperative lymphatic mapping (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 the initial node or nodes show no sign of cancer cells, there is a high likelihood that lymph nodes further along the chain 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 proteins (MBR; CD206) present on the surface of immune cells. Lymphoseek is a macromolecule consisting of multiple units of diethylene triamine pentaacetic acid (DTPA) and mannose, 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 Phase 3 clinical studies NEO3-05 and NEO3-09 in subjects with breast cancer or melanoma, Lymphoseek demonstrated highly effective lymph node identification and significant benefits over an approved comparator agent, vital blue dye (VBD). Importantly, Lymphoseek missed significantly less cancer-positive lymph nodes, resulting in nearly 10% of subjects in these Phase 3 clinical studies being up-staged by the use of Lymphoseek who would have been under-staged using VBD alone.

In clinical study NEO3-06 in head and neck squamous cell carcinoma, the primary endpoint was based on the number of subjects with cancer-positive lymph nodes following a multiple level lymph node dissection. Among the total of 83

subjects evaluated in the trial, Lymphoseek accurately identified 38 of 39 subjects who had pathology-positive lymph nodes, for an overall false negative rate (FNR) of 2.56%, which was statistically significant (p=0.0205), meeting the statistical threshold for success of the primary endpoint of the study.

In the U.S., ILM has also historically employed a non-standard, Technetium 99mTc-labeled radiopharmaceutical agent known as sulfur-colloid (TcSC), often used in place of, or in addition to, VBD. 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 Lymphoseek provided significantly greater performance in breast cancer patients 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. 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.

Similar meta-analyses have been performed with Lymphoseek melanoma and head and neck cancer data from the Phase 3 studies NEO3-05, NEO3-09, and NEO3-06 to compare Lymphoseek's performance against TcSC performance. Pooled data from melanoma patients enrolled in NEO3-05 and NEO3-09 was compared to published retrospective and prospective data for melanoma ILM with TcSC submitted for U.S. regulatory review. Through this analysis, Lymphoseek was shown to identify at least one hot SLN in 98% of patients, whereas TcSC identified at least one hot SLN in 96.4%, a difference that was statistically significant ($p=0.0014$). Lymphoseek also identified more hot nodes per patient than TcSC: 2.38 vs 1.70 ($p<0.0001$).

In head and neck cancer, Lymphoseek's performance in the NEO3-06 study was compared to the performance of TcSC as published in the American College of Surgeons Oncology Group (ACOSOG) study Z-0360. The FNR for TcSC was 0.10 (95% CI=0.027,0.231) compared to an FNR for Lymphoseek of 0.03 (95% CI=0.001,0.138), a difference that was statistically significant ($p<0.0006$). The accuracy for TcSC was 0.97 (95% CI=0.928,0.992) versus an accuracy for Lymphoseek of 0.99 (95% CI=0.934,1.000), again a difference that was statistically significant ($p<0.0161$). Based on these meta-analyses of clinical data, Lymphoseek provided statistically significantly better performance than TcSC in the key metrics of FNR and accuracy in head/neck squamous cell carcinoma.

In June 2012, we published data developed from the NEO3-05 and NEO3-09 Phase 3 trials of Lymphoseek demonstrating important performance characteristics of Lymphoseek compared to a European commercially available radiolabeled colloid used in intra-operative lymphatic mapping. The analysis evaluated the performance of Lymphoseek in breast cancer patients 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 on Nanocoll's performance in breast cancer patients 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). 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 ($p < 0.0001$). In September 2012, we announced the presentation of related data at the European Society of Surgical Oncology annual meeting. 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].

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

- Improved detection of 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, involving the removal of as many as 20 to 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. Application to head and neck cancer is a focus of our sNDA under review at FDA with the PDUFA target date of June 16, 2014.

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 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. A third Phase 3 trial involving subjects with head and neck squamous cell carcinoma was completed in 2013.

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) 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 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 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 two Phase 3 clinical trials of Lymphoseek in melanoma in the Annals of Surgical Oncology showing strong lymph node identification properties.

Lymphoseek was approved and indicated for use in lymphatic mapping procedures in breast cancer and melanoma by the FDA in March 2013.

Clinical research continued with a Phase 3 trial involving subjects with head and neck squamous cell carcinoma (NEO3-06) which was initiated in June 2009. The NEO3-06 clinical study was designed to demonstrate the performance of Lymphoseek in head and neck cancer as well as to potentially expand the product label for Lymphoseek as a SLNB agent after the initial marketing clearance for the product. 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 to enable us to conduct a pre-planned interim analysis. The interim analysis compared the pathological analysis of the sentinel lymph nodes localized using Lymphoseek with that of all the lymph nodes removed during a multiple level nodal dissection surgery of the head and neck. This multiple level nodal 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.

In April 2013, the Company announced top-line results from the NEO3-06 clinical study. Results of the interim analysis demonstrated that Lymphoseek met the primary efficacy endpoint of accurately identifying sentinel lymph nodes (SLNs) in subjects with squamous cell carcinoma of the head, neck or mouth, as compared to the removal of all lymph nodes during multiple level nodal dissection surgery of the head and neck. The primary endpoint for the NEO3-06 trial was based on the number of subjects with pathology-positive lymph nodes (that is, lymph nodes found to harbor cancer) following a multiple level lymph node dissection and required a minimum of 38 subjects whose lymph nodes contained pathology-confirmed disease. The FNR of 2.56% was statistically significant and met the statistical threshold for success of the primary endpoint. FNR is the rate of occurrence of negative test results in subjects known to have metastatic disease in the lymph nodes, for which the individual is being tested. These findings indicate that Lymphoseek accurately identified SLNs in these trial subjects, and is likely to be predictive of overall node pathology status. On the basis of the strong safety and efficacy data observed in the interim analysis, an assessment of subject risk:benefit in the trial, and a consideration of potential benefit to head and neck cancer patients at large, the independent Data Safety Monitoring Committee (DSMC) for the NEO3-06 trial recommended terminating enrollment and closing the study. Subsequently, based on results from the NEO3-06 study, results from other studies already completed, the recommendation of the independent DSMC, and a constructive meeting with the

FDA on our findings, we officially closed the NEO3-06 study.

In September 2013, results from the NEO3-06 study conducted at The Ohio State University Comprehensive Cancer Center - James Cancer Hospital & Solove Research Institute were published in the peer-reviewed journal, JAMA Otolaryngology Head and Neck Surgery, a publication of the American Medical Association. The publication, “Use of a Novel Receptor-Targeted (CD206) Radiotracer, 99m-Tc-Tilmanocept, and SPECT/CT for Sentinel Lymph Node Detection in Oral Cavity Squamous Cell Carcinoma: Initial Institutional Report in an Ongoing Phase 3 Study,” describes the experience at one of the clinical trial sites that participated in NE03-06. The results, published independently by this single clinical trial site in our larger Phase 3 NE03-06 study, corroborate data for the ability of Lymphoseek to identify sentinel lymph nodes in head and neck squamous cell carcinoma.

In October 2013, we announced additional results from the fully completed NEO3-06 study indicating that Lymphoseek also met all other pre-specified study endpoints, including sensitivity, negative predictive value (NPV) and overall accuracy relative to the pathology status of non-SLNs. Lymphoseek demonstrated a sensitivity rate of 97.6%, a NPV of 97.8%, and overall accuracy of 98.8%. No differences were observed in the ability of Lymphoseek to detect SLNs between same-day or subsequent-day surgery following Lymphoseek injection.

Moreover, multiple level nodal dissection of patients in the trial with cancer-positive lymph nodes led to an average removal of 38 lymph nodes per patient, whereas Lymphoseek on average led to the identification of approximately 4 lymph nodes. This reduction in potential lymph node removal could lead to a substantial reduction in potential morbidity for patients with head and neck cancer undergoing sentinel lymph node biopsy, as well as potentially enabling reductions in the time and cost of surgery.

In December 2013, the FDA granted fast track designation to Lymphoseek for sentinel lymph node detection in patients with head and neck cancer and we submitted a sNDA with the FDA seeking approval for the marketing and sale of Lymphoseek for the same indication. In assessing the application, the FDA chose to separate the filing into two applications based on the proposed labeling extensions requested and the scope of information provided. The first sNDA, aimed at Lymphoseek's use as a sentinel lymph node detection agent in patients with head and neck cancer, was accepted for review by the FDA in February 2014, and was granted a priority review. Under PDUFA, the FDA has set a target review date for the first Lymphoseek sNDA in June 2014. In March 2014, the FDA accepted for review the second sNDA to support a broader and more flexible use of Lymphoseek in imaging and lymphatic mapping procedures, including lymphoscintigraphy and other optimization capabilities. Under PDUFA, the FDA has set a target review date for the second sNDA in October 2014.

We are currently pursuing registration of Lymphoseek in the European Union (EU). In February 2012, Navidea was advised 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. In December 2013, the EMA provided updated feedback on the MAA as it continued its review. The updated feedback was limited to supplemental product specification data and the NEO3-06 Phase 3 study in head and neck cancer. Based on the cumulative feedback to date, we anticipate the CHMP could take up consideration of the MAA early in 2014. A positive opinion for approval would enable commercialization in the EU subsequent to European Commission (EC) adoption of the CHMP opinion and pricing determinations on a country-by-country basis in each member state, a process which could take several months. However, 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.

Manocept Platform

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. Macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. This flexible and versatile platform acts as an engine for purpose-built molecules that may enhance diagnostic accuracy, clinical decision-making and ultimately patient care, while offering the potential to utilize a breadth of diagnostic modalities, including SPECT, PET, intra-operative and/or optical-fluorescence detection. The Company's FDA-approved precision diagnostic lymphatic mapping agent, Lymphoseek, is representative of the ability to successfully exploit this mechanism to develop powerful new diagnostic agents.

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In September 2013, we presented collaborative data at the Cancer Advance Conference at Harvard Medical School from the proof-of-principle imaging studies using Cy3-tilmanocept, a fluorescent-labeled agent derived from the Manocept platform, utilizing the technical principles underlying Lymphoseek. Data presented at the conference establish the feasibility of using Manocept compounds to bind to the CD206 mannose receptor and target macrophage inflammatory cells, an approach that may enable the design of novel immune cell-targeted agents for diagnosis and disease staging. These studies focused on establishing the ability of fluorescent Cy3-tilmanocept to target macrophages in two disease states which are representative of a broader set of disorders which involve macrophages: Kaposi's Sarcoma (KS) and tuberculosis (TB), both outside the current lymphatic mapping application. These data support the expansion of the Manocept platform into potential new indications in disorders that are mediated by, or associated with, macrophages utilizing immune-cell targeting to address unmet diagnostic needs in this emerging area. Other recognized disorders having macrophage involvement include not only KS and TB, but also rheumatoid arthritis (RA), Systemic Lupus Erythematosis, atherosclerosis/vulnerable plaque, Crohn's disease and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, and inflammation. These data were published in a special supplement, Nature Outlook: Medical Imaging, in the October 31, 2013 issue of Nature. The supplement included a White Paper entitled Innovations in receptor-targeted precision imaging at Navidea: Diagnosis up close and personal. The online edition also includes several peer-reviewed articles published previously by Nature Publishing Group that reinforce the principle of CD206 mannose receptor targeting using Manocept compounds to identify macrophages.

In November 2013, we announced our collaboration with investigators at the University of California, San Francisco (USCF), on a clinical study to evaluate, for the first time, the use and performance of technetium–labeled tilmanocept in patients with KS. The investigator–initiated study will evaluate HIV patients with various stages of KS who will be administered 99mTc-tilmanocept and assessed by SPECT imaging for localization of KS lesions and possible identification of KS disease spread.

In February 2014, data utilizing compounds from our Manocept platform in models of RA were presented by Thomas Rosol, DVM, PhD, DACVP from The Ohio State University at a Keystone Symposia on Molecular Cell Biology of Macrophages in Human Disease held in Santa Fe, NM. The poster presentation, entitled "Imaging of macrophages in immune-mediated inflammatory disease and cartilage antibody-induced arthritis in mice using Cy3-tilmanocept" highlights research from Dr. Rosol and other Navidea collaborators at The Ohio State University. The studies demonstrate the ability of Cy3-tilmanocept to identify and localize to disease-state macrophages when administered intravenously, enabling detection of immune-mediated arthritis in affected joints in vivo in mice. Results were confirmed using histopathology. The data highlighted the identification of immune-mediated inflammation seen in arthritic elbows and knees of arthritis-affected mice but not in control mice or un-affected joints within arthritic mice. The imaging results in this study showed preferential localization of macrophages by Cy3-tilmanocept in affected joints with little to no localization in unaffected joints. As the mannose receptor is a key portal for imaging pathological states of macrophage-associated inflammation, the Manocept-derived molecules are potentially potent tools for addressing unmet needs in this area such as identifying, staging, assessing disease activity and monitoring therapeutic efficacy.

The Company continues to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform. We cannot assure you that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance. 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 NAV4694, 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 AD and potentially also MCI. 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.

Although these other agents constitute a step forward, each has potential limitations. Navidea's NAV4694 tracer appears to have several important advantages, including the ability to generate clean images with less white matter uptake to enable identification of lower levels of amyloid, making the images easier to read and interpret and potentially facilitating earlier detection of disease.

NAV4694 Clinical Development

NAV4694 has been studied in rigorous pre-clinical studies and clinical trials in humans. Clinical studies through Phase 3 have included over 180 subjects to date and have included subjects with mild cognitive impairment (MCI), 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 recently completed US enrollment in a Phase 2 trial that we initiated in September 2012, primarily to understand the diagnostic performance of NAV4694 and to

expand the safety database for the compound. We also initiated a Phase 2b trial in subjects with MCI 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.

In July 2013 at the Alzheimer's Association International Conference (AAIC), it was announced that the Australian Imaging, Biomarker & Lifestyle Flagship Study of Ageing (AIBL) plans to switch to NAV4694 for use in its comprehensive research initiative in Alzheimer’s disease and MCI from a PET imaging agent for ß-amyloid detection that for many has remained the accepted benchmark standard for studies investigating Alzheimer’s disease and differential diagnoses of dementia. Recently published results from a head-to-head study that directly compared NAV4694 to the accepted standard agent PiB demonstrated that NAV4694 displayed nearly identical imaging characteristics, and is accessible and affordable and can be reliably interpreted in a variety of clinical settings.

Also at the 2013 AAIC, researchers at the McGill Centre for Studies in Aging, Douglas Research Institute, and Montreal Neurological Institute presented results of a post-mortem brain tissue study comparing performance characteristics of NAV4694 to this accepted standard PiB, concluding that NAV4694 better differentiated amyloid deposition associated with AD in post-mortem brains.

In August 2013, we signed an agreement with Siemens PETNET Solutions that grants PETNET Solutions the right to manufacture NAV4694 for our clinical trials. Under the terms of the agreement, PETNET Solutions will initially manufacture NAV4694 clinical trial material at select U.S. radiopharmacies, with the possibility of expanding into additional Siemens' PETNET Solutions locations in the future.

Also in August 2013, we were awarded a Small Business Innovation Research (SBIR) grant from the National Institute on Aging (NIA) of the National Institutes of Health (NIH) in connection with our Phase 3 clinical program for NAV4694 as an aid in the differential diagnosis of Alzheimer's disease. The SBIR grant has the potential to provide up to $1.8 million in support, if fully funded, through the conclusion of the Phase 3 clinical study. Funding of $259,000 for the approved first stage of the grant is intended to provide support for initiation activities of the Phase 3 clinical program. Funding of the second stage of the grant is contingent upon meeting specific aims related to the first stage of the grant such as institutional review board approval of the Phase 3 protocol, clinical site contracting and investigator training.

In September 2013, we were awarded an additional SBIR grant from the NIA of the NIH in connection with the evaluation of NAV4694 as a diagnostic imaging agent that may aid physicians in identifying those individuals with MCI who are at greatest risk of progressing to AD. The grant has the potential to provide up to $2.3 million in support, if fully funded, through the conclusion of the clinical study. Funding of $152,000 for the approved first stage of the grant is intended to provide support for initiation activities of the clinical trial program. Funding of the second stage of the grant is contingent upon meeting specific aims related to the first stage of the grant such as clinical site contracting, investigator training and institutional review board approvals.
In February 2014, we announced that NAV4694 produced highly differentiated images in the first cohort of subjects enrolled in our Phase 2b PET imaging study of subjects with MCI. The subjects were enrolled and evaluated at the Alzheimer's Disease Center at Quincy Medical Center, Quincy, MA. The results indicate that NAV4694 produced high-quality diagnostic images that segregated MCI subjects into two discrete groups, either amyloid-positive or amyloid-negative. The image evaluation was performed on twelve subjects meeting pre-defined inclusion/exclusion criteria for emerging, or early-stage, cognitive impairment. NAV4694 scans were assessed by two independent readers using a 3-point visual scale. Image interpretation used the Company's proprietary visual-read algorithm. All twelve MCI subjects segregated into either amyloid-positive or amyloid-negative categories. The technical quality of the scans was good and both raters were in complete agreement on the 3-point scale, with 8 scans highly positive for ß-amyloid and 4 scans negative. There were no intermediate ratings or ambiguous cases despite the early-stage characterization of the subjects' cognitive impairment status. The scans were easy to read and the readers noted that the high gray matter relative to white matter signal made image interpretation very straight forward. To date, the product candidate appears to be safe and well-tolerated. Results are expected to be presented at an upcoming scientific conference on AD. We cannot assure you, however, that further clinical trials for this product will be successful, that the product 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, which was extended to July 31, 2012, to complete due diligence. 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 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 approximately 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 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 initiated a Phase 2b program in DLB in April 2013, commencing an investigator-initiated study. In December 2013, we announced that the first subject had been enrolled in a pivotal Phase 3 clinical trial to assess the safety and efficacy of NAV5001 as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor. This clinical study will focus on subjects with emerging symptoms in whom diagnostic uncertainty and unmet need are highest. Results from earlier trials using NAV5001 suggest that it may be an effective, well-tolerated imaging agent. The high affinity for DAT with resulting clear images can assist physicians in reaching an accurate diagnosis sooner, and the rapid kinetics with minimal time between injection and scanning and time in the SPECT scanner not only decrease patient exposure and but also facilitate increased efficiency with potential cost savings for the nuclear medicine facility. Reducing diagnostic uncertainty and error rates for patients with movement disorders who often exhibit similar clinical symptoms has the potential to afford great value, especially early in the initial clinical presentation, and may lead to improved clinical decision-making and patient management.

In August 2013, we reached agreement with the FDA for two special protocol assessments (SPAs) for the Company's pivotal Phase 3 program with NAV5001 as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor. The SPAs are written agreements between the Company, as the program's sponsor, and the FDA regarding the design, endpoints and statistical analysis for the two pivotal Phase 3 clinical trials to be used in support of a potential NAV5001 NDA. The Company is actively preparing for the initiation of the pivotal Phase 3 trials later this year. The international, open-label, pivotal NAV5001 Phase 3 program consists of two similar clinical trials that will run in parallel and enroll approximately 550 total subjects who exhibit early stage tremor. Each Phase 3 trial was the subject of a SPA with the FDA. The primary endpoint of both studies is to evaluate the relative diagnostic efficacy of the NAV5001 SPECT images compared with the diagnosis made by neurologists and that established by a consensus panel of three movement disorder specialists as the 'Standard of Truth.' In one study, each subject will undergo SPECT imaging with NAV5001 only. In the second study, subjects will undergo SPECT imaging with both NAV5001 and an alternative SPECT agent, ioflupane, in a cross-over comparison design. In December 2013 we enrolled our first subject for the studies. We cannot assure you, however, that further clinical trials for this product will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance. See Risk Factors.

NAV1800 (formerly RIGScan)

NAV1800 is a radiolabeled, cancer-specific targeting monoclonal antibody intended to enable identification of cancerous tissue and delineate tumor or occult or metastatic cancerous tissue. NAV1800 is administered to the patient and is potentially identified by imaging or, during surgery with a gamma detection probe, thereby assisting a surgeon in identifying the location of cancerous tissues.

Our NAV1800 technology is a radiolabeled monoclonal antibody that serves as the biologic targeting agent for detection of occult or metastatic cancer. The antibody localizes or binds to a tumor antigen called TAG-72 expressed on many solid tumor cancers. NAV1800 is intended to aid in identifying a primary tumor, ascertaining margins, or determining the extent and location of occult and metastatic tumor in patients with solid tumor cancers that express the TAG-72 antigen, such as colorectal cancer, ovarian cancer, prostate cancer, lung 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.

NAV1800 Clinical Development

The murine monoclonal antibody of NAV1800 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 NAV1800 for the detection of metastatic colorectal cancer based primarily on results of a single Phase 3 clinical trial, NEO2-14. The FDA declined approval, indicating that, in addition to identifying additional pathology-confirmed disease, the clinical studies of NAV1800 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 support resuming NAV1800 development, we filed a new IND request with the FDA in late 2010. In a pre-IND meeting with the FDA in February 2011, the FDA provided guidance regarding our manufacturing process, to increase manufacturing efficiency and the quality of the underlying biologic antibody and potentially transitioning from a murine-based monoclonal antibody to a human-based monoclonal antibody. In August 2011, we also held a meeting with the SAWP of the EMA and received similar guidance. With this collective guidance, we transitioned from a murine monoclonal antibody used in the previous studies noted above to a humanized monoclonal antibody.

In September 2012, we were awarded a grant from the NIH to further develop NAV1800. 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 completion of the first phase, development of a protocol, and institutional review board approval, will be for an additional $1.2 million.

We have focused over the last several years on manufacturing and quality of the humanized antibody with the aim of completing the necessary steps to support clinical development. Rigorous CMC evaluation must be completed as a pre-requisite to clinical trials to ensure the antibody is adequate for human study. NAV1800 is a biologic drug that has not been produced for several years. We will need to establish robust manufacturing and radiolabeling capabilities for the antibody in order to meet the regulatory needs for the NAV1800 product. Additional non-clinical studies could potentially be required by regulatory authorities. We cannot assure you, however, that if further clinical trials for this product proceed, that if they proceed that they will be successful, that the product will achieve regulatory approval, or if approved, that it will achieve market acceptance. See Risk Factors.

In November 2013, we initiated a collaboration with investigators at the University of Alabama at Birmingham (UAB) on a potential clinical study to evaluate the safety and efficacy of NAV1800 in cancer patients. The study is intended to evaluate up to 20 patients with colorectal cancer by administering NAV1800 and assessing by SPECT/CT imaging for the presence of liver metastasis, as well as evaluate other parameters of the performance of the radiolabeled antibody. Investigators at UAB have published extensively on the use of TAG-72 targeted monoclonal antibodies in the cancer setting. As the scope and required resources for the NAV1800 program continues to be assessed, particularly in light of other development opportunities such as Lymphoseek, NAV4694, NAV5001, our Manocept platform, or other agents, the timing and scope of our plans for NAV1800 may be further affected.

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 586,000 deaths in 2014 in the U.S. alone. The NIH has estimated the overall annual costs for cancer for the U.S. for 2009 at $216.6 billion: $86.6 billion for direct medical costs and $130.0 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 1.1 million new cases will occur in the U.S. in 2014.

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 1.9% in women under age 49 to 6.7% in women age 70 or older. While the incidence rate for breast cancer appears to be stable, the overall number of new cases of breast cancer is still increasing. According to the ACS, over 233,000 new cases of invasive breast cancer are expected to be diagnosed during 2014 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 76,000 new cases of melanoma will be diagnosed in the U.S. during 2014. In addition to breast cancer and melanoma, we believe that our oncology products may have utility in other cancer types with over another 1 million new cases expected during 2014 in the U.S. Additionally, the ACS estimates that approximately 1.7 million new cancer cases will be diagnosed in the U.S. during 2014.

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 5.2 million Americans had AD in 2013. On a global basis, Alzheimer's Disease International estimated in 2013 that there were 44.4 million people living with dementia. AA estimates that total costs for AD care was approximately $203 billion in 2013 and is expected to rise to $1.2 trillion by 2050. AA also estimates that there are over 15.4 million AD and dementia caregivers providing 17.5 billion hours of unpaid care valued at over $216.4 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 2000-2010, death rates have declined for most major diseases while deaths from AD have risen 68 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 MCI 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.

During the fourth quarter of 2007, we executed an agreement with Cardinal Health Inc.'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.

In May 2013 the Company announced the commercial launch of Lymphoseek in the U.S. through a distribution agreement with Cardinal Health. Although Cardinal Health is responsible for the sale and distribution of Lymphoseek to health care professionals, we work closely with Cardinal Health in supporting marketing activities and conducting medical education programs for Lymphoseek. Although it is early in the launch, we believe we are seeing positive signs in measures of success we believe are critical when introducing a novel product such as Lymphoseek and which we believe indicate a successful initial launch.

In August 2013, we announced that the Centers for Medicare and Medicaid Services (CMS) issued a Healthcare Common Procedure Coding System (HCPCS) pass-through C Code for Lymphoseek. We anticipate that the reimbursement code, which became effective on October 1, 2013, will streamline the billing and reimbursement process for hospital providers who use Lymphoseek and support its fair and equitable reimbursement. Lymphoseek has also been granted a permanent A Code effective January 1, 2014. We believe these developments may assist in advancing utilization of Lymphoseek.

We are aiming to deploy a specialty pharmaceutical strategy to commercialization of Lymphoseek, particularly in Europe, that would be supportive of premium product positioning, as opposed to a commodity or a generics positioning approach. Unlike the U.S., where institutions typically rely on radiopharmaceutical products which are compounded and delivered by specialized radiopharmacy distributors such as Cardinal Health, institutions in Europe predominantly purchase non-radiolabeled material and compound the radioactive product on-site. In November 2013, we announced that we had selected Norgine BV and affiliates (Norgine), a leading European specialty pharmaceutical company, as our partner for Europe and certain other territories in Africa and Austral-Asia, subject to the completion of a definitive agreement. We have not yet completed a definitive agreement with Norgine and cannot assure you that we will be successful in reaching a definitive agreement, or if secured, that we will be able to maintain a successful relationship with Norgine, on terms acceptable to the Company, or at all.

Also, in November 2013, Navidea completed an agreement with Enigma Biomedical Group for the distribution of Lymphoseek in Canada, affording local access to that market as well. In January 2014, we entered into a distribution agreement for Lymphoseek in Taiwan with Global Medical Solutions Taiwan, Ltd. (GMST), a leading in-country distributor of nuclear medicine and diagnostic imaging products. The companies will work together to address all needed Taiwanese FDA regulatory requirements and expect local approval in 2014-15. Prior to complete regulatory

approval, in appropriate situations, the product will be made available in accordance with named-patient mechanisms. The agreement anticipates distribution of non-radioactive kits as well as unit-dose product which will be radiolabeled at the GMST commercial radiopharmacy, affording flexibility in meeting the needs of end users in the Taiwanese market. We have also recently commenced shipment of Lymphoseek to select medical centers in the Middle East. We believe that with international partnerships to complement our position in the U.S., we will help establish Lymphoseek as a global leader in lymphatic mapping, as we are aware of no other company which has this global geographic range.

We currently have no distribution agreements for NAV4694, NAV5001 or NAV1800. In addition, it should be noted that the distribution model we have established with Cardinal Health in the U.S. for Lymphoseek may not necessarily be applicable to other markets or even our other potential radiopharmaceutical candidates due to differences in regional distribution infrastructure, regulation and medical practice patterns. We cannot assure you that we will be successful in securing collaborative partners for other global markets or radiopharmaceutical products, or that we will be able to negotiate acceptable terms for such arrangements.

Manufacturing

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

Lymphoseek Manufacturing

Reliable produces the drug substance and OsoBio performs 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 ^{99m}Tc to become the final form of Lymphoseek to be administered to a patient. Both organizations have assisted Navidea in the preparation of the chemistry, manufacturing and control (CMC) sections of our submissions to the FDA and the EMA. Both Reliable and OsoBio are registered manufacturers with the FDA and 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. In September 2013, we entered into a Manufacturing Services Agreement with OsoBio for contract pharmaceutical development, manufacturing, packaging and analytical services for Lymphoseek. The agreement is through December 2016, and automatically renews for additional two-year periods. We cannot assure you that we will be successful in completing future agreements for the supply of Lymphoseek on terms acceptable to the Company, or at all.

NAV4694 Manufacturing

Supplies of NAV4694 used in clinical development through Phase 2b were manufactured by AstraZeneca through various arrangements. In May 2012, we executed an agreement with Molecular NeuroImaging, LLC (MNI) to produce and distribute NAV4694 to imaging centers within a specified geographic region. In October 2012, we completed an agreement with Spectron mrc, LLC (Spectron) to produce NAV4694 for use at certain clinical trial sites. In August 2013, we entered into a Manufacturing Services Agreement with PETNET Solutions, Inc. (PETNET) for the manufacture and distribution of NAV4694 with an initial term of 3 years. Under the terms of the agreement, PETNET will initially manufacture NAV4694 clinical trial material at select U.S. radiopharmacies, with the possibility of expanding into additional PETNET locations in the future. We cannot assure you that we will be successful in executing future 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., a Canadian corporation and well-recognized manufacturer of ^{123}I and nuclear medicine labeled imaging agents. In May 2013, we entered into an agreement with Nordion (Canada) Inc. (Nordion) to produce and supply NAV5001 for our late-phase clinical trials. Nordion will radiolabel NAV5001, manage the manufacturing logistics, and ship it to third-party clinical trial sites on behalf of Navidea. The initial three-year term expires in May 2016. We cannot assure you that we will be successful in executing future agreements for the supply of NAV5001 on terms acceptable to the Company, or at all.

NAV1800 Manufacturing

We will need to re-establish robust CMC and radiolabeling capabilities for the antibody in order to meet the regulatory needs for the NAV1800 product. We cannot assure you that we will be successful in completing the necessary development, manufacturing or supply processes or agreements to support NAV1800 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 fluorbetapir, 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. In October 2013, the FDA approved flutemetamol, under the name Vizamyl, for adults being evaluated for AD and dementia with PET brain imaging. In December 2013, the EMA CHMP recommended approval of florbetaben for Alzheimer's diagnosis.

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 in the EU 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.

NAV1800 Competition

We do not believe there are any intraoperative diagnostic radiopharmaceuticals directly competitive with NAV1800 that would be used in the colorectal cancer application to which NAV1800 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 NAV1800.

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 2 patent families totaling 17 patents and patent applications in the United States and certain major foreign markets. The patents and patent applications held by The Regents of the University of California 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 major-market 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. and certain major foreign markets related to manufacturing processes for Lymphoseek, the first of which was issued in the U.S. in 2013. 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 covering the [^{18}F]NAV4694 drug substance and NAV4694 Precursor 214.

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 2 issued patents, each expiring in 2030, and 1 patent application pending in the U.S., and 9 patent applications pending in 3 foreign jurisdictions.

NAV1800 Intellectual Property

We continue to support proprietary protection for the products related to NAV1800 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 potential partners. 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, Public Health Service Act, 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 Atomic Energy 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 current good clinical practices (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 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. Lymphoseek was approved and indicated for use in lymphatic mapping for breast cancer and melanoma by the FDA in March 2013. Additional trials, one in head and neck cancer which was recently closed, and an ongoing trial in colorectal cancer, are anticipated to provide additional data to potentially support expansion of Lymphoseek utilization 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. In December 2013, the FDA granted fast track designation to Lymphoseek for sentinel lymph node detection in patients with head and neck cancer and we submitted a sNDA with the FDA seeking approval for the marketing and sale of Lymphoseek for the same indication. In assessing the application, the FDA chose to separate the filing into two applications based on the proposed labeling extensions requested and the scope of information provided. The first sNDA, aimed at Lymphoseek’s use as a sentinel lymph node detection agent in patients with head and neck cancer, was accepted by the FDA in February 2014 and was granted a priority review for the expanded use. Under PDUFA, the FDA has set a target review date for the first Lymphoseek sNDA in June 2014. In March 2014,

the FDA accepted the second sNDA to support a broader and more flexible use of Lymphoseek in imaging and lymphatic mapping procedures, including lymphoscintigraphy and other optimization capabilities. Under PDUFA, the FDA has set a target review date for the second sNDA in October 2014. 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 5600 Blazer Parkway, Suite 200, Dublin, OH 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-29 of this Form 10-K.

Research and Development

We spent approximately $23.7 million, $16.9 million, and $15.2 million on research and development activities in the years ended December 31, 2013, 2012 and 2011, respectively.

Employees

As of February 28, 2014, we had 57 full-time and 8 part-time employees. We consider our relations with our employees to be good.

Item 1A. Risk Factors

An investment in our common stock is highly speculative, involves a high degree of risk, and should be made only by investors who can afford a complete loss. You should carefully consider the following risk factors, together with the other information in this prospectus, including our financial statements and the related notes, before you decide to buy our common stock. Our most significant risks and uncertainties are described below; however, they are not the only

risks we face. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading of our common stock could decline, and you may lose all or part of your investment therein.

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 in March 2013. Additional trials, one in head and neck cancer (NEO3-06) which is the focus

of a sNDA that now has a PDUFA target date of June 16, 2014, an ongoing trial in colorectal cancer and other planned investigator-sponsored trials, are anticipated to provide additional support for the potential expansion of Lymphoseek utilization into multiple other cancer types. A second sNDA aimed at expanding the Lymphoseek label to support more flexible utilization practices for Lymphoseek in lymphatic mapping and lymphoscintigraphy imaging has a PDUFA target date of October 16, 2014. We began generating revenues from product sales of Lymphoseek in the second quarter of 2013. As we continue to 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, the Manocept platform, and NAV1800 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, NAV1800, products based on our Manocept platform, 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 a number 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, Alzheimer’s disease, Parkinson’s and other diseases 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 sourced or in-licensed from third parties, consisting of Lymphoseek, NAV4694, NAV5001, the Manocept platform, and NAV1800. 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. The Phase 3 clinical trials served as the basis for the approval of Lymphoseek in March 2013. We successfully completed a third Phase 3 clinical trial for Lymphoseek in subjects with head and neck cancer in 2013, the results of which are anticipated to provide support for the potential expansion of the product labeling for Lymphoseek to address other cancer types or potentially the enhanced indication for sentinel lymph node biopsy in certain cancers.

With respect to NAV4694, AstraZeneca completed clinical development through a Phase 2a level. We are currently supporting a Phase 2 trial that we initiated in September 2012, primarily to expand the safety database for the compound, and a Phase 2b trial in subjects with MCI initiated in March 2013. In June 2013, we initiated a Phase 3 autopsy-based trial to support registration in the U.S. and the EU.

With respect to NAV5001, Alseres completed five clinical trials in over 600 subjects. Alseres received a Phase 3 SPA from the FDA for NAV5001 in 2009. We initiated a Phase 2b program in DLB in April 2013, commencing an investigator-initiated study. We also initiated a Phase 3 trial in subjects with PD in December 2013. Each Phase 3 trial is the subject of a SPA agreement with the FDA.

We continually assess our clinical trial plans and may, from time to time, initiate additional clinical trials to support our overall strategic development objectives. 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 March 2013 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.

In August 2013, we announced that the CMS issued a HCPCS “C Code” for Lymphoseek. We anticipate that the reimbursement code, which became effective on October 1, 2013, will streamline the billing and reimbursement process for hospital providers who use Lymphoseek and support its fair and equitable reimbursement. The pass-through provisions supporting this C Code are expected to extend through December 31, 2015. Lymphoseek has also been granted a permanent “A Code” effective January 1, 2014. We believe these developments may assist in advancing utilization of Lymphoseek. However, there can be no assurance that, following the expiration of the

pass-through provisions, we will be successful in establishing or obtaining a separately reimbursable status for 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 third-party clinical manufacturing capabilities for our radiopharmaceutical compounds under development. 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 a manufacturing agreement with 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, revenues from Lymphoseek may be adversely impacted, In addition, clinical trials for our other product candidates 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 for which Eli Lilly received FDA approval in 2012. Florbetapir also received marketing authorization in the EU in January 2013. We are also aware of two additional first-generation beta-amyloid imaging agents in late stages of development by two other large pharmaceutical companies, florbetaben from Piramal Enterprises, Imaging Division, and flutemetamol from GE Healthcare. In October 2013, the FDA approved flutemetamol, under the name Vizamyl, for adults being evaluated for AD and dementia with PET brain imaging. In December 2013, the EMA CHMP recommended approval of florbetaben for Alzheimer's diagnosis. 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 NAV1800, 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 the underlying intellectual property for Lymphoseek, NAV4694, NAV5001 and NAV1800. 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 or protection related to our intellectual property if diligence requirements are not met, or at the expiry of underlying patents.

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.

Our currently held and licensed patents expire over the next one to sixteen years. Expiration of the patents underlying our technology, in the absence of extensions or other trade secret or intellectual property protection, may have a material and adverse effect on us.

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, Alseres, and the University of California Board of Regents, 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 NAV1800, 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 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. 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. 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 UCSD, AstraZeneca, 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.

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 (the Oxford Loan Agreement) with Oxford Finance, LLC (Oxford).

In addition to the security interest in our assets, the Oxford Loan Agreement carries 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 upon the exercise of the warrants issued in connection with the Oxford Loan Agreement;
- we provide certain financial information and reports to Oxford in a timely manner; and
- we indemnify Oxford against certain liabilities.

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

- making any material dispositions of our assets, except for permitted dispositions;
- making any changes in our business, management, ownership, or business locations;
- entering into any merger or consolidation without Oxford's consent;
- acquiring or making investments in any other person other than permitted investments;
- incurring any indebtedness, other than permitted indebtedness;
- granting or permitting liens against our assets, other than permitted liens; declaring or paying any dividends or making any other distributions; or
- entering into any material transaction with any affiliate, other than in the ordinary course of business;.

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

In addition, our Loan Agreement (the Platinum Loan Agreement) with Platinum-Montaur Life Sciences, LLC (Platinum) carries covenants typical for commercial loan agreements, and similar to those contained in the Oxford Loan 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 Platinum Loan Agreement, permitting Platinum to terminate our ability to obtain additional draws under the Platinum Loan Agreement and accelerate the maturity of the debt. Such actions by Platinum could materially adversely affect our operations, results of operations and financial condition, including causing us to substantially curtail our product development activities.

Platinum may exercise its conversion right, and that could dilute your ownership and the net tangible book value per share of our common stock.

Platinum may exercise the right to convert all or any portion of the unpaid principal or unpaid interest (the Conversion Amount) accrued on any draw advanced by Platinum under the Platinum Loan Agreement on or after June 25, 2013, beginning on a date that is two years from the date on which such draw was advanced, and thereafter at any time while any portion of such draw is outstanding, into shares of Navidea's common stock. Platinum may also exercise a conversion right on the amount of any mandatory repayment due following the Company achieving $2,000,000 in cumulative revenues from sales or licensing of Lymphoseek. The conversion option applies to the Conversion Amount if the Company is prohibited from making such repayment under the terms of the Subordination Agreement between Platinum, Oxford and the Company. If Platinum exercises any or all of its conversion rights, the percentage ownership of our current stockholders will be reduced. The issuance of additional common stock may also result in dilution in the net tangible book value per share of our common stock. The $3.2 million outstanding under the

Platinum credit facility as of December 31, 2013 is not subject to the conversion option.

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 continuing contentious and partisan federal budget negotiations 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 continuing federal budget disputes 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, 2013, the Company had a stockholders' deficit of approximately $4.0 million. Even if an issuer has a stockholders' deficit, 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 $1.11 per share and as high as $3.59 per share during the 12-month period ended February 28, 2014. 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.

During the 12-month period beginning on March 1, 2013 and ending on February 28, 2014, the average daily trading volume for our common stock on the NYSE MKT was approximately 1.1 million shares. We cannot 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 25,000 square feet of office space at 5600 Blazer Parkway, Dublin, Ohio, as our principal offices. The current lease term expires in October 2022, at a monthly base rent of approximately $24,000 during 2014. We must also pay a pro-rata portion of the operating expenses and real estate taxes of the building. We also lease approximately 6,000 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 in March 2015, at a monthly base rent of approximately $10,000 during 2014. 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. The prices set forth below reflect the quarterly high and low sales prices for shares of our common stock during the last two fiscal years.

	High	Low
Fiscal Year 2013:		
First Quarter	$3.59	$2.42
Second Quarter	2.80	2.26
Third Quarter	3.31	2.57
Fourth Quarter	2.71	1.11
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

As of February 28, 2014, we had approximately 700 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.

On December 23, 2013, we issued 1,461,690 shares of our common stock to Platinum Montaur Life Sciences, LLC (Platinum) in exchange for 447 shares of our Series B Convertible Preferred Stock in connection with Platinum's exercise of its conversion option pursuant to the terms of our Series B Convertible Preferred Stock. The conversion terms for this issuance were 3,270 shares of our common stock in exchange for each share of our Series B Convertible Preferred Stock. The issuance of these securities was exempt from registration under Section 3(a)(9) of the Securities Act.

There were no repurchases of our common stock during the three-month period ended December 31, 2013.

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, 2008 through December 31, 2013. This graph assumes an investment in the Company's common stock and the indices of $100 on December 31, 2008 and that all dividends were reinvested.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Navidea Biopharmaceuticals, the Russell 3000 Index, and the NASDAQ Biotechnology Index
*$100 invested on 12/31/2008 in stock or index, including reinvestment of dividends.

	Cumulative Total Return as of December 31,					
	2008	2009	2010	2011	2012	2013
Navidea Biopharmaceuticals	100.00	214.04	361.40	459.65	496.49	363.16
Russell 3000	100.00	125.46	143.96	142.64	162.58	212.89
NASDAQ Biotechnology	100.00	115.63	132.98	148.69	196.12	324.80

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,				
	2013	2012	2011	2010	2009
Statement of Operations Data:					
Revenue	$1,131	$79	$598	$617	$—
Cost of goods sold	333	—	—	—	—
Research and development expenses	23,710	16,890	15,154	8,941	4,380
Selling, general and administrative expenses	15,526	11,178	9,548	4,353	3,028
Loss from operations	(38,438)	(27,989)	(24,104)	(12,677)	(7,408)
Other expenses, net	(4,261)	(1,168)	(943)	(43,567)	(35,891)
Benefit from income taxes	—	—	7,880	2,135	1,256
Loss from continuing operations	(42,699)	(29,157)	(17,167)	(54,109)	(42,043)
Discontinued operations, net of tax effect	—	—	22,780	4,144	2,437
Net (loss) income	(42,699)	(29,157)	5,613	(49,965)	(39,606)
Preferred stock dividends	—	(43)	(100)	(8,207)	(240)
(Loss) income attributable to common stockholders	$(42,699)	$(29,200)	$5,513	$(58,172)	$(39,846)
(Loss) income per common share (basic and diluted):					
Continuing operations	$(0.35)	$(0.29)	$(0.17)	$(0.77)	$(0.57)
Discontinued operations	$—	$—	$0.23	$0.05	$0.03
(Loss) income attributable to common stockholders	$(0.35)	$(0.29)	$0.06	$(0.72)	$(0.54)
Shares used in computing (loss) income per common share: (1)					
Basic and diluted	121,809	99,060	90,509	80,726	73,772

	As of December 31,				
	2013	2012	2011	2010	2009
Balance Sheet Data:					
Total assets	$40,317	$11,972	$31,194	$10,863	$9,018
Long-term obligations	33,035	7,187	6,714	2,787	13,485
Accumulated deficit	(317,257)	(274,558)	(245,357)	(250,870)	(192,699)

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(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. Toward that end, we are currently developing five pharmaceutical platforms:

- Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help evaluate patients with 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. It was approved by the U.S. Food and Drug Administration (FDA) in March 2013, and launched commercially in the United States in May 2013.
- Navidea's Manocept™ platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. This flexible and versatile platform acts as an engine for the design of purpose-built molecules offering the potential to be utilized across a range of diagnostic modalities, including single photon emission computed tomography (SPECT), positron emission tomography (PET), intra-operative and/or optical-fluorescence detection in a variety of disease states.
- NAV4694 is a Fluorine-18 (F-18) radiolabeled 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 (I-123) radiolabeled SPECT imaging agent being developed as an aid in the diagnosis of Parkinson's disease (PD) and other movement disorders, with potential use as a diagnostic aid in dementia.
- NAV1800 (formerly 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.

The last four of these drug product platforms 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 execute 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, as well as more recently on our other pipeline programs, including NAV4694, NAV5001, NAV1800, and our Manocept platform. We expect our overall research and development expenditures to be higher during 2014 as compared to 2013 due to the advances in our clinical, regulatory, and business development programs and activities, as well as personnel, contractors and consultants that support the global registration and commercialization of Lymphoseek, further development of NAV4694, NAV5001, NAV1800, and our Manocept platform. The level to which the expenditures rise will depend on the scope,

requirements and timing of these strategic development initiatives in different territories around the world.

Our efforts in 2013 and to date in 2014 have resulted in the following milestone achievements:

Corporate/Financial

- Completed two underwritten public offerings totaling 3.6 million shares of common stock in February and April 2013, resulting in net proceeds to the Company of approximately $9.3 million.
- Drew $4 million under the $50 million credit facility with Platinum. Platinum also exercised certain warrants in March 2013, providing $1.4 million in proceeds.

- Closed on a $25 million debt financing transaction led by GE Capital, Healthcare Financial Services in June 2013.
- Completed a $30 million registered direct offering of common stock led by Crede CG III, Ltd. (Crede), a wholly-owned subsidiary of Crede Capital Group, LLC, a U.S.-based accredited, institutional investor, in September 2013.
- Executed a $30 million debt financing transaction with Oxford Finance LLC in March 2014, resulting in full payoff of the GE Capital debt and providing increased access to our working capital.
- Appointed Dr. Thomas Tulip President, in addition to his continuing duties as Chief Business Officer, effective in May 2013. Dr. Mark Pykett retained the title of Chief Executive Officer.
- Appointed Dr. Michael M. Goldberg and Perry A. Karsen to our Board of Directors in November 2013 and February 2014, respectively.

Pipeline

- Lymphoseek

Launched Lymphoseek in May 2013 with Cardinal Health, following the March 2013 approval by the FDA. Lymphoseek is indicated for use in lymphatic mapping for breast cancer and melanoma and will be sold and distributed by Cardinal Health to health care professionals in the United States through its network of nuclear pharmacies.

Reported top-line data from the planned interim analysis of the NEO3-06 Phase 3 head and neck cancer clinical study of Lymphoseek demonstrating that Lymphoseek met its primary endpoint in identification of sentinel lymph nodes as compared to the gold standard of pathology assessment of multi-level node resection.

Published results of Lymphoseek Phase 3 clinical trials in breast cancer in Annals of Surgical Oncology showing that Lymphoseek met its primary efficacy endpoint in assessment of lymphatic mapping performance in patients with breast cancer.

Announced commencement of an investigator-initiated study by Maimonides Medical Center to evaluate the utility of Lymphoseek in lymphatic mapping procedures for colorectal cancer.

Researchers highlighted results from Lymphoseek clinical trials in 20 presentations and a sponsored lymphatic mapping symposium at the Joint International Oncology Congress, the Annual Meeting of the American Society of Clinical Oncology and the Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) including the utilization of Lymphoseek to asses SLN in head and neck cancer patients and the evaluation of human mannose receptor (CD206) binding of Lymphoseek.

Announced presentation of results from two Lymphoseek and radiolabeled colloid studies in lymphatic mapping for breast cancer at SNMMI.

Announced results from Lymphoseek study on accuracy of lymph node detection from injection time to surgery.

Announced presentation of meta-analysis results of Lymphoseek and ACOSOG radiolabeled colloid in head and neck cancer.

Closed enrollment in the NEO3-06 study in head and neck cancers following a constructive FDA meeting and made plans to submit a sNDA based on the current interim data analysis.

CMS issued a Lymphoseek reimbursement pass-through C Code that became effective October 1, 2013, establishing a reimbursement mechanism for healthcare providers.

Researchers highlighted additional results from a Lymphoseek Phase 3 clinical trial in head and neck cancer at the American College of Surgeons 2013 Annual Clinical Congress. Lymphoseek successfully identified sentinel lymph nodes when compared with the pathology gold standard to meet the primary and secondary endpoints.

Independent investigators at The Ohio State University published Lymphoseek Phase 3 clinical trial results in JAMA Otolaryngology Head and Neck Surgery.

The FDA granted fast track designation to Lymphoseek for sentinel lymph node detection in patients with head and neck cancer.

Submitted a sNDA with the FDA seeking approval for the marketing and sale of Lymphoseek for sentinel lymph node detection in patients with head and neck cancer, and a second sNDA to support a broader and more flexible use of

Lymphoseek in imaging and lymphatic mapping procedures, including lymphoscintigraphy and other optimization capabilities.

- Manocept Platform

Data focused on CD206 receptor-targeted precision diagnostic imaging for multiple disorders using agents from the recently announced Manocept platform were featured in Nature Outlook: Medical Imaging and appeared in the October 31, 2013 issue of Nature.

The Manocept Advisory Board was formed and is comprised of renowned scientific and medical advisors in the field of macrophage science and macrophage-mediated diseases as Navidea seeks to prioritize and advance encouraging early stage results.
Announced collaboration with investigators at USCF on a clinical study to evaluate the use and performance of technetium–labeled tilmanocept in patients with KS.

- NAV4694

Published results from a NAV4694 clinical trial in the Journal of Nuclear Medicine demonstrating positive head-to-head comparison of NAV4694 and PiB, the academic gold standard imaging biomarker for AD and dementia -amyloid imaging. The study was conducted by collaborators at Austin Health in Melbourne, Australia.
Commenced enrollment in a Phase 2b, open-label, safety and efficacy PET imaging study of NAV4694 for detection of cerebral -amyloid in subjects diagnosed with MCI.
Completed a study of NAV4694 as a biomarker for visual detection and quantification of cerebral -amyloid in diagnosing AD, a study designed and conducted by Navidea's partner, AstraZeneca.
Navidea's global Phase 3 trial of NAV4694 was initiated with the first patient enrolled at the Southern Illinois University School of Medicine.
AIBL, a leading Australian-based neurodegenerative disease and imaging research consortium, announced that it is converting to NAV4694 from gold standard PiB for its comprehensive research initiative in AD and MCI.
Researchers from the McGill Centre for Studies in Aging, Douglas Research Institute, and Montreal Neurological Institute presented results at the annual Alzheimer's Association International Conference showing NAV4694 better differentiated amyloid deposition associated with AD in post-mortem brains than PiB. Navidea co-sponsored the 2013 Alzheimer's Imaging Consortium in July which featured leading international experts including presentations by Drs. Gil Rabinovici, University of California, San Francisco and Christopher Rowe, Austin Health, Melbourne, Australia.
Christopher Rowe et al published results in the Journal of Nuclear Medicine from a NAV4694 clinical trial demonstrating positive results from a head-to-head comparison of NAV4694 and -amyloid imaging gold standard PiB in AD and dementia. The study was conducted by collaborators at Austin Health in Melbourne, Australia.
Two NIH SBIR grants were awarded for studies of NAV4694 in MCI and for the Phase 3 program in AD. The grants have the potential to provide up to $4.1 million in support, if fully funded.
U.S. manufacturing and supply agreement for clinical trial doses of NAV4694 was signed with Siemens' PETNET Solutions.

- NAV5001

Enrolled the first subject in a clinical study to investigate the performance of NAV5001 in a SPECT imaging procedure of the brain in connection with Navidea's program to evaluate NAV5001 in DLB.
A manufacturing and supply agreement with Nordion was executed to produce and distribute supplies of ^{123}I-labeled NAV5001 for late-phase clinical trials.
A clinical study commenced to investigate the performance of NAV5001 in a SPECT imaging procedure of the brain in connection with Navidea's program to evaluate NAV5001 in DLB.
Special Protocol Assessments for the NAV5001 Phase 3 program were agreed upon with the FDA.
Obtained a new patent covering the formulation of NAV5001. The patent is set to expire in 2031.
Enrolled the first subject in one of the two planned NAV5001, pivotal Phase 3 clinical trials. The trial assesses the safety and efficacy of NAV5001 as an aid in the differential diagnosis of Parkinsonian syndromes from non-Parkinsonian tremor.

- NAV1800

Announced collaboration with investigators at UAB on a clinical study to evaluate the safety and activity NAV1800. The study will evaluate up to 20 patients with colorectal cancer by administering NAV1800 and assessing by SPECT/CT imaging for the presence of liver metastasis.

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Our Outlook

In connection with the U.S. approval of Lymphoseek in March 2013, the Company has now undertaken the initial stages of commercial launch in the U.S. with our marketing partner, Cardinal Health, with an official announcement of launch in May 2013. We began reporting revenue from Lymphoseek beginning in the second quarter of 2013, though revenue for the second quarter consisted primarily of inventory stocking of Cardinal Health's nuclear pharmacies. Our sales margins since launch have reflected the negative impact of the comparatively higher proportion of sales of lower-margin inventory stocking units and testing activities associated with launch and required by the FDA. Our longer-term expectations for gross margins will increase as these charges diminish in proportion to revenue, and continue to be in line with previous estimates. As insight into the sales process with Lymphoseek has grown over the initial quarters of sales, we anticipate revenue to Navidea from Lymphoseek will be between $5 million and $6 million during 2014. We expect to update this guidance on a quarterly basis over the remainder of 2014, augmented where possible by data from certain primary metrics with which to assess Lymphoseek's performance. The Company currently believes Lymphoseek has the potential to achieve a market leadership position among lymphatic mapping agents in the U.S. by mid-2015.

Following the sale of the GDS Business, our entire organization has been primarily focused on the development of radiopharmaceutical agents that are intended to assist us in fulfilling our vision of becoming a leader in precision diagnostics. Our operating expenses in recent years have been focused primarily on support of Lymphoseek, NAV4694 and NAV5001 product development, and to a lesser extent, on efforts to restart active development of NAV1800. In addition, we began initial evaluation of our Manocept platform in 2013.We spent approximately $23.7 million, $16.9 million, and $15.2 million in total on research and development activities in the years ended December 31, 2013, 2012 and 2011, respectively. 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	2013	2012	2011
Lymphoseek	$4,702,829	$5,632,183	$5,286,395
Manocept platform	503,338	—	—
NAV4694	7,812,602	3,339,592	5,018,490
NAV5001	2,602,461	2,159,483	—
NAV1800	156,577	253,325	1,302,851

Due to the advancement of our efforts with Lymphoseek, our Manocept platform, NAV4694, NAV5001, and NAV1800, we expect our total drug-related research and development expenses for 2014 to increase to approximately $25 million to $30 million. The levels of program expenditures will depend in part on efforts associated with advancing Lymphoseek and accelerating enrollment and other activities related to our NAV4694 program. In general, development expenses for Lymphoseek in 2014 are expected to decrease as compared to 2013; expenses in some other programs are anticipated to increase in 2014 over 2013, primarily driven by NAV4694, and to a lesser extent, Manocept. We expect expenses for NAV5001 to be largely steady and commensurate with our available resources. Expenses related to NAV1800 may increase in 2014 from 2013, but in a manner consistent with funding available under our NIH SBIR grant.

Lymphoseek was approved and indicated for use in lymphatic mapping in patients with breast cancer and melanoma by the FDA in March 2013. During 2014, we expect to continue to incur significant general marketing support as well as medical education expenses related to Lymphoseek. Although our marketing partner will bear the direct marketing, sales and distribution costs related to the sale of Lymphoseek, we expect to incur ongoing costs to support product launch and medical education-related and market outreach activities associated with Lymphoseek commercialization. We expect to incur additional development expenses related to supporting the MAA review of Lymphoseek in the EU

and support the other product, regulatory, manufacturing and commercial activities related to the potential marketing registration and sale of Lymphoseek in other markets. Additionally, we anticipate that we will incur costs related to the FDA review and advancement of our two Lymphoseek sNDAs. 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 in the U.S. or any other market.

We are currently evaluating existing and emerging data on the potential use of Manocept-related agents in the diagnosis and disease-staging of disorders in which macrophages are involved such as KS, TB, RA and other disease states, to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform. In the near-term, our development efforts with respect to the Manocept platform will likely be limited to such evaluations. We will also be evaluating potential funding and other resources required for continued development, regulatory approval and commercialization of any Manocept

platform product candidates that we identify for further development. We cannot assure you that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

We expect to incur significant expenses for NAV4694 during 2014 related to ongoing Phase 2 clinical trials 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. We also expect to incur significant expenses for NAV5001 during 2014, primarily in support of our Phase 3 clinical trials, as well as for manufacturing-related activities required to support our clinical trial and registration efforts. Currently, neither NAV4694 nor NAV5001 is expected to contribute revenue to the Company until at least 2017. We cannot assure you that further clinical trials for these products will be successful, that the agents will ultimately achieve regulatory approval, or if approved, the extent to which they will achieve market acceptance. During 2013, we were awarded two SBIR grants from the NIA in connection with our Phase 3 clinical programs for NAV4694, the first as an aid in the differential diagnosis of AD and the second as a diagnostic imaging agent that may aid physicians in identifying individuals with MCI who are at greatest risk of progressing to AD. These SBIR grants have the potential to provide up to $1.8 million and $2.3 million in support, respectively, if fully funded, through the conclusion of the Phase 3 clinical studies.

We are in the process of evaluating the business, manufacturing, development and regulatory pathways forward with respect to NAV1800. In the near-term, our development efforts related to NAV1800 will likely be limited to those which we are able to fund through external sources such as the SBIR grant from the NIH we were awarded in 2012. We believe that the time required for continued development, regulatory approval and commercialization of a NAV1800 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 NAV1800 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 agent will ultimately achieve regulatory approval, or if approved, that it will 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 2013 or 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 present these results as 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 only recently began generating commercial revenue, the discussion of our operating variances focuses primarily on our radiopharmaceutical development programs and the supporting general and administrative expenses.

Years Ended December 31, 2013 and 2012

Net Sales and Margins. Net sales of Lymphoseek were $614,000 during 2013. We did not record any sales revenue during the same period in 2012. Gross margins on net sales of Lymphoseek were 46% for the year ended 2013. Cost of goods sold included a royalty on net sales payable under our license agreement with UCSD. During the year ended December 31, 2013, margins on Lymphoseek sales were negatively impacted due to the proportion of sales made up of lower margin inventory-stocking units, coupled with post-production testing activities at launch, required by regulatory authorities, which are charged as one-time period costs, including certain post-manufacture testing costs related to normal ongoing processes required by the FDA.

Grant and Other Revenue. During 2013, we recognized $440,000 of grant revenue related to SBIR grants from the NIH to support NAV4694 and NAV1800 development. Grant revenue of $76,000 was received from Ohio Third Frontier and provided $50,000 toward the development of alternative uses of Lymphoseek and $26,000 supporting student internships. During the year ended December 31, 2012, we recognized $60,000 of revenue related to reimbursement of certain Lymphoseek commercialization activities by our distribution partner, Cardinal Health, and $19,000 related to Ohio Third Frontier grants supporting student internships.

Research and Development Expenses. Research and development expenses increased $6.8 million, or 40%, to $23.7 million during 2013 from $16.9 million during the same period in 2012. The increase was primarily due to net increases in drug project expenses related to (i) increased NAV4694 development costs of $4.5 million including increased clinical trial costs coupled with increased manufacturing-related activities, (ii) increased Manocept platform development costs of $503,000, and (iii) a net increase in NAV5001 development costs of $443,000 including increased clinical trial costs and manufacturing-related activities of $1.9 million, offset by a decrease in licensing fees of $1.4 million; offset by (iv) a net decrease in Lymphoseek development costs of $929,000 resulting from decreased manufacturing-related costs, decreased EMA filing fees and regulatory consulting costs primarily related to filing a MAA in 2012, and decreased clinical trial costs, offset by increased costs of $2.2 million related to sNDA submissions for two additional Lymphoseek indications in 2013 and (v) decreased consulting costs related to potential pipeline products of $407,000. The net increase in research and development expenses also included increased compensation including incentive-based awards and other related expenses of $2.6 million related to increased headcount required for expanded development efforts, as well as increased travel and other support costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $4.3 million, or 39%, to $15.5 million during 2013 from $11.2 million during the same period in 2012. The net increase was primarily due to increased medical education costs to support Lymphoseek of $2.6 million, increased compensation including incentive-based awards and other expenses of $1.3 million related to increased headcount, and increased investor relations, legal and professional services costs, offset by decreased out-of-pocket marketing costs related to the commercial launch of Lymphoseek of $1.3 million.

Other Income (Expense). Other expense, net, was $4.3 million during 2013 as compared to $1.2 million during the same period in 2012. Interest expense increased $1.6 million to $2.8 million during 2013 from $1.2 million for the same period in 2012, primarily due to the interest related to the GECC/MidCap loan as well as the draws on the Platinum credit facility, offset by the decreased balance of the Hercules note payable. Of this interest expense, $765,000 and $545,000 in 2013 and 2012, respectively, was non-cash in nature related to the amortization of debt issuance costs and debt discounts related to the GECC/MidCap and Hercules notes. During 2013, we recorded losses on extinguishment of debt of $943,000 related to the modification of the Platinum note and $429,000 upon paying off the balance of the Hercules note. For the years ended December 31, 2013 and 2012, we recorded non-cash expense of $112,000 and income of $32,000, respectively, related to changes in the estimated fair value of financial instruments.

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 NAV1800 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.

Liquidity and Capital Resources

Cash balances increased to $32.9 million at December 31, 2013 from $9.1 million at December 31, 2012. The net increase was primarily due to net proceeds from the issuance of common stock of $39.6 million, net proceeds from the GECC/MidCap note payable of $23.8 million, and draws on our Platinum credit facility of $4.0 million, offset by cash used to fund our operations, mainly for research and development activities, of $35.6 million, principal payments on our notes payable of $6.0 million, purchases of equipment of $1.2 million, and payment of employee minimum tax withholdings related to stock-based compensation of $659,000. The current ratio increased to 3.3:1 at December 31, 2013 from 1.7:1 at December 31, 2012.

Operating Activities. Cash used in operations increased $11.7 million to $35.6 million during the year ended December 31, 2013, compared to $23.9 million during the same period in 2012. Cash used in operations increased $7.9 million to $23.9 million during 2012 compared to $16.0 million during 2011.

Accounts receivable increased to $1.2 million at December 31, 2013 from $18,000 at December 31, 2012, primarily due to receivables due from the landlord of our Dublin office space for tenant improvements, from Cardinal Health for sales of Lymphoseek and from the NIH for SBIR grants. There was no material change in accounts receivable during 2012 compared to 2011.

Inventory levels increased to $2.2 million at December 31, 2013, from $298,000 at December 31, 2012. Increases in work-in-process and finished goods were related to in-process and completed new lots of Lymphoseek finished drug. Increases in materials were related to purchases of Lymphoseek drug substance. We expect inventory levels to increase during 2014 as we produce additional Lymphoseek inventory to support commercial sales following our recent product launch. 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.

Prepaid expenses and other current assets decreased to $1.0 million at December 31, 2013 from $1.2 million at December 31, 2012, primarily due to the utilization of prepayments to our third party manufacturers of Lymphoseek inventory. 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.

Accounts payable increased to $2.4 million at December 31, 2013 from $1.4 million at December 31, 2012, primarily due to increases in Lymphoseek and NAV5001 development activities, coupled with normal fluctuations in timing of receipt and payment of invoices. Accrued liabilities and other current liabilities increased to $4.8 million at December 31, 2013 from $2.0 million at December 31, 2012, primarily due to increases in accrued NAV4694 development costs and net increases in compensation-related accruals. 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. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our level of commercial activity related to Lymphoseek, and development activity related to the Manocept platform, NAV4694, NAV5001, NAV1800, and other potential product candidates.

Investing Activities. Investing activities used $1.3 million during 2013 compared to $672,000 used during 2012 and $27.2 million provided during 2011. 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 $1.2 million during 2013 were primarily for equipment to be used in the production of NAV4694 and Lymphoseek, leasehold improvements, computers, and software. 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. Payments for patent and trademark costs were $53,000, $8,000 and $53,000 during 2013, 2012 and 2011, respectively.

Financing Activities. Financing activities provided $60.7 million during 2013 compared to $5.1 million during 2012 and $11.1 million during 2011. The net $60.7 million provided by financing activities in 2013 consisted primarily of proceeds from the issuance of common stock of $41.3 million and proceeds from notes payable of $29.0 million, offset by principal payments on our notes payable of $6.0 million, payment of common stock issuance costs of $1.8 million, payment of debt issuance costs of $1.2 million, and payment of minimum tax withholdings related to stock-based compensation of $659,000. 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. 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 and $7.0 million of proceeds from notes payable, offset by $2.8 million paid for tax withholdings primarily related to the separation of our former President and CEO, David Bupp.

Platinum and the Bupp Investors

In 2011 and 2012, Platinum converted 917 and 3,063 shares, respectively, of Series B Preferred Stock into 2,998,590, and 10,016,010 shares, respectively, of the Company’s common stock. In November 2012, pursuant to a Securities Exchange Agreement with the Company, Platinum Partners Value Arbitrage Fund, L.P. (PPVA), an affiliate of Platinum, exchanged 3,001,860 shares of our common stock for 918 shares of Series B Preferred Stock, effectively reversing a portion of the earlier conversions. In June 2013, the Company and Platinum entered into a Warrant Exercise Agreement, pursuant to which Platinum exercised its Series X Warrant and Series AA Warrant for 2,364.9 shares of the Series B Preferred Stock, which are convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share). In 2013, Platinum converted 1,737.9 shares of Series B Preferred Stock into 5,682,933 shares of the Company’s common stock. As of December 31, 2013, there were 7,565 shares of Series B Preferred Stock outstanding which were convertible into 24,737,550 shares of our common stock.

In December 2012, we entered into a Waiver Agreement (the Waiver) pursuant to which Platinum and PPVA, 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 was to remain in effect until December 31, 2013, upon which date all outstanding shares of Series B Preferred Stock were to automatically convert into common stock pursuant to the terms of the Certificate. In addition, we amended the terms of Platinum'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. Following this conversion, no shares of Series C Preferred Stock remained outstanding, and the Company filed a Certificate of Elimination with the Delaware Secretary of State eliminating from the Company's Amended and Restated Certificate of Incorporation all reference to the Series C Preferred Stock.

In June 2013, we amended the Series B Preferred Stock to eliminate the date certain for automatic conversion. As a result of this amendment, all outstanding shares of Series B Preferred Stock will automatically convert into common stock of the Company at the conversion rate of 3,270 shares of common stock for each share of Series B Preferred Stock upon the earlier to occur of either of the following: (i) the closing of a firm commitment underwritten public offering of common stock of the Company pursuant to an effective registration statement under Section 5 of the Securities Act in which the gross case proceeds to the Company (before underwriting discounts, commissions and fees) from such public offering are at least $10,000,000, or (ii) one hundred eighty (180) days following the first trading date upon which the price per share of the common stock equals or exceeds $7.00 per share, but excluding from such 180-day period any trading day on which the price is less than $5.00 per share.

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, Platinum 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, Platinum 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.

Platinum Credit Facility

In July 2012, we entered into an agreement with Platinum to provide us with a credit facility of up to $50 million (the Platinum Loan Agreement). Following the approval of Lymphoseek, Platinum was 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 (discussed below) plus 0.125%. Through June 25, 2013, we drew a total of $8.0 million under the original facility. The agreement also provides for Platinum to extend an additional $15 million on terms to be negotiated. Principal amounts were due the earlier of two years from the date of draw or June 30, 2016.

In June 2013, in connection with entering into the GECC/MidCap Loan Agreement (discussed below), the Company and Platinum entered into an Amendment to the Platinum Loan Agreement (the First Platinum Amendment). Navidea, Platinum, and GECC/MidCap also entered into a Subordination Agreement, providing for subordination of the Company’s indebtedness under the Platinum Loan Agreement to the Company’s indebtedness under the GECC/MidCap Loan Agreement, among other customary terms and conditions.

Concurrent with the execution of the First Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the First Amended Platinum Note) to Platinum, which amended and restated the original promissory note issued to Platinum, in the principal amount of up to $35 million. The First Amended Platinum Note also adjusted the interest rate 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 GECC/MidCap Loan Agreement plus 0.125% (effective interest rate at December 31, 2013 was 10%). In addition, the First Platinum Amendment granted Platinum the right, at Platinum’s option subject to certain conditions, to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draw (the Conversion Amount), beginning on a date two years from the date the draw is advanced, into the number of shares of Navidea’s common stock computed by dividing the Conversion Amount by a conversion price equal to the lesser of (i) 90% of the lowest VWAP for the 10 trading days preceding the date of such conversion request, or (ii) the average VWAP for the 10 trading days preceding the date of such conversion request. The First Platinum Amendment also provided a conversion right on the same terms with respect to the amount of any mandatory repayment due following the Company achieving $2,000,000 in cumulative revenues from sales or licensing of Lymphoseek. The conversion option applies to the Conversion Amount if the Company is prohibited from

making such prepayment under the terms of the Subordination Agreement.

Also in connection with the First Platinum Amendment, the Company and Platinum entered into a Warrant Exercise Agreement (Exercise Agreement), pursuant to which Platinum exercised its Series X Warrant and Series AA Warrant. The warrants were exercised on a cashless basis by canceling a portion of the indebtedness outstanding under the Platinum Loan Agreement equal to $4,781,333, the aggregate exercise price of the warrants. Pursuant to the Exercise Agreement, in lieu of common stock, Platinum received on exercise of the warrants 2,364.9 shares of the Company's Series B, convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share).

During 2013, we drew a total of $4.0 million under the Platinum credit facility and recorded interest expense of $468,000 associated with this credit facility. As of December 31, 2013, the remaining outstanding principal balance was $3.2 million, with $31.8 million still immediately available under the credit facility.

In March 2014, in connection with entering into the Oxford Loan Agreement (discussed below), we repaid all amounts outstanding under the GECC/MidCap Loan Agreement and entered into a second amendment to the Platinum Loan Agreement (the Second Platinum Amendment). Concurrent with the execution of the Second Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the Second Amended Platinum Note) to Platinum, which amended and restated the First Amended Platinum Note. The Second Amended Platinum Note adjusted the interest rate to the greater of (i) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (ii) 10.0%, and (iii) the highest rate of interest then payable by the Company pursuant to the Oxford Loan Agreement plus 0.125%. Navidea, Platinum, and Oxford also entered into a Subordination Agreement, providing for subordination of the Company's indebtedness under the Platinum Loan Agreement to the Company's indebtedness under the Oxford Loan Agreement, among other customary terms and conditions.

Warrant Exercises

During 2011, the holders of Series CC warrants, which were issued in 2010, 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, which were also issued in 2010, 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 2013 or 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 Hercules 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 Hercules Loan Agreement, we issued Hercules: (1) a Secured Term Promissory Note in the principal amount of $7,000,000 (the Hercules Note), 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%, 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 warrants). Additionally, the Hercules 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 had an obligation to provide the additional $3,000,000. The Hercules Loan Agreement provided for an interest-only period beginning on December 29, 2011 and expiring on July 1, 2012. The principal and interest was to be repaid in 30 equal monthly installments, payable on the first of each month following the expiration of the

interest-only period. The outstanding balance of the debt was due December 1, 2014. Navidea had 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 had 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 was collateralized by a security interest in substantially all of the Company's assets except for intellectual property, as to which the security interest was in rights to income or proceeds from the sale or licensing thereof. The Hercules Loan Agreement also specified 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 and recorded interest expense of $1.9 million on the Hercules Note, which includes amortization of the debt discount and issuance costs.

During the period from January 1, 2013 through June 24, 2013, we paid $1.3 million of principal payments and recorded interest expense of $472,000 on the Hercules Note, which included amortization of the debt discount and issuance costs. On June 25, 2013, the Company used a portion of the proceeds from the GECC/MidCap Note (discussed below) to pay the remaining $4.4 million of principal outstanding on the Hercules Note, as well as a $250,000 end-of-term fee and a $66,000 early payment penalty in accordance with the terms of the Hercules Loan Agreement. As of December 31, 2013, the Hercules Note was no longer outstanding. The Series GG warrants remained outstanding as of December 31, 2013.

GECC/MidCap Debt

In June 2013, we executed a Loan and Security Agreement (the GECC/MidCap Loan Agreement) with General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap), providing for a loan to the Company of $25 million. Pursuant to the Loan Agreement, we issued GECC and MidCap: (1) Term Notes in the aggregate principal amount of $25,000,000, bearing interest at 9.83% (the GECC/MidCap Notes), and (2) Series HH warrants to purchase an aggregate of 301,205 shares of our common stock at an exercise price of $2.49 per share, expiring in June 2023 (the Series HH warrants). The GECC/MidCap Loan Agreement provided for an interest-only period beginning on June 25, 2013 and expiring on June 30, 2014. The principal and interest was to be repaid in 30 equal monthly installments, payable on the first of each month following the expiration of the interest-only period, and one final payment in an amount equal to the entire remaining principal balance of the Term Note on the maturity date. The outstanding balance of the debt was due December 23, 2016. On the date upon which the outstanding principal amount of the loan was paid in full, the Company was required to pay a non-refundable end-of-term fee equal to 4.0% of the original principal amount of the loan. The debt was collateralized by a security interest in substantially all of the Company’s assets except for intellectual property, as to which the security interest was in rights to income or proceeds from the sale or licensing thereof. The Loan Agreement also specified certain covenants including the requirement that Navidea maintain a minimum cash balance greater than six times its monthly cash burn amount and provide certain information, such as financial statements and budgets, on a periodic basis. As of December 31, 2013, the minimum cash balance required was $22.6 million, and we were in compliance with all covenants of the Loan Agreement. During 2013, we recorded interest expense of $1.8 million on the GECC/MidCap Notes, which included amortization of the debt discount and issuance costs. As of December 31, 2013, the remaining outstanding principal balance of the debt was $25.0 million, and the Series HH warrants remained outstanding. On March 4, 2014, in connection with the consummation of the Oxford Loan Agreement, we repaid all amounts outstanding under the GECC/MidCap Loan Agreement upon the receipt by GECC/MidCap of a payoff amount of $26,708,791.67. The payoff amount included payments of: (1) $500,000 as a pre-payment fee; and (2) $1,000,000 as an end-of-term final payment fee.

Oxford Debt

In March 2014, we executed a Loan and Security Agreement the (Oxford Loan Agreement) with Oxford Finance, LLC (Oxford), providing for a loan to the Company of $30 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) Term Notes in the aggregate principal amount of $30,000,000, bearing interest at 8.5% (the Oxford Notes), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of $1.918 per share, expiring in March 2021 (the Series KK warrants). We will make monthly payments of interest only commencing on April 1, 2014, and continuing on the first calendar day of each successive month thereafter through and including the first calendar day of the month immediately preceding April 1, 2015 (the Amortization Date, which may be extended to April 1, 2016, and again to April 1, 2017, if the Company achieves certain milestones associated with the Company’s Lymphoseek product). Commencing on the Amortization Date, and continuing on the first calendar day of each month thereafter, the Company will make consecutive equal monthly payments of principal and interest, in arrears, to the lenders then party to the Oxford Loan Agreement based on a repayment schedule of 48 months if the Amortization Date is April 1, 2015, 36 months if the Amortization Date is

April 1, 2016, and 24 months if the Amortization Date is April 1, 2017. All unpaid principal, and accrued and unpaid interest, with respect to the Oxford Notes is due and payable in full on March 1, 2019. We will also make a final payment to the lenders in an aggregate amount equal to the original principal amount of loan multiplied by 7.95% if the Amortization Date is April 1, 2015; 8.95% if the Amortization Date is extended to April 1, 2016; or 9.95% if the Amortization Date is extended to April 1, 2017. The Oxford Notes are 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 Oxford Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including, without limitation, financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Oxford Loan Agreement.

2013 Public Offerings

In February 2013, we completed a public offering of 1,542,389 shares of the Company's common stock at a price of $3.10 per share (the February 2013 Offering). The net proceeds to the Company were approximately $4.5 million after deducting expenses associated with the February 2013 Offering. In April 2013, we completed another public offering of 2,100,000 shares of the Company's common stock at a price of $2.43 per share (the April 2013 Offering). The net proceeds to the Company were approximately $4.8 million after deducting expenses associated with the April 2013 Offering. The February 2013 and April 2013 Offerings were underwritten by Ladenburg Thalmann & Co. Inc. and were made pursuant to the Company's existing effective shelf registration statement on Form S-3.

In September 2013, we entered into a Securities Purchase Agreement with Crede for a registered direct public offering of 10,563,381 shares of our common stock at a price of $2.84 per share for total gross proceeds of $30.0 million. In addition to the common stock, we issued Series JJ warrants to purchase 3,169,015 shares of our common stock at an exercise price of $3.83 per share, expiring in September 2016.

Crede can exercise the Series JJ warrants at any time at a strike price of $3.83. The warrant agreement also provides for the potential exchange of warrants into Navidea common stock for no additional consideration starting six months after the date of the Securities Purchase Agreement if, at the time of the exchange, the closing bid price for Navidea's common stock is below $3.83. The amount of shares issuable on a potential exchange is calculated by dividing a Black-Scholes valuation of the warrants by the closing bid price for Navidea's common stock on the date of the exchange. However, as a number of the key inputs to the Black-Scholes calculation are fixed under the terms of the warrant agreement, the Company does not expect the Black-Scholes valuation on the date of a potential exchange to vary materially from the derivative liability of $7.7 million which was initially recorded related to the Series JJ warrants. Based on this valuation, the Company has estimated the number of shares issuable on a potential exchange to be between 2.1 million shares (based on a potential exchange price of $3.83) and 3.8 million shares (based on the floor exchange price of $2.00). The Series JJ warrants remained outstanding and had an estimated fair value of $7.7 million as of December 31, 2013.

The net proceeds to the Company were approximately $28.8 million after deducting expenses associated with the Securities Purchase Agreement, including placement agent fees of $999,000 (3.3% of the gross proceeds). The common stock, warrants, and shares of common stock underlying the warrants were issued pursuant to the Company's existing effective shelf registration statement on Form S-3.

Summary

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 believe that our current cash balance, our credit facility with Platinum, our projected revenue derived from U.S. sales of Lymphoseek, our ability to control expenses, the potential for partnership funding, and the potential to access capital markets through our shelf registration, though we have no current intent to raise funds through approaching the equity capital markets, provide us with 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, strategic needs, and balance sheet requirements. We cannot assure you that if we attempt to raise additional capital through debt, royalty, equity or otherwise, 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.

Recent Accounting Developments

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-02, Comprehensive Income (Topic 220). ASU 2013-02 provides entities with two basic options for reporting the effect of significant reclassifications – either (1) on the face of the statement where net income is presented or (2) as a separate footnote disclosure. Public entities will report reclassifications in both annual and interim periods. Under option 1, the effect of significant reclassifications is presented parenthetically by component of other comprehensive income (OCI) on the respective line items of net income. Entities must also parenthetically report the aggregate tax effect of reclassifications in the income tax expense (benefit) line item. Under option 2, the significant amounts of each component of OCI must be presented in a single footnote. ASU 2013-02 is effective prospectively for reporting periods beginning after December 15, 2012. ASU 2013-02 did not have an effect on our consolidated financial statements.

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (ASU 2013-11). ASU 2013-11 requires an entity to present an unrecognized tax benefit in the financial statements as a reduction to a deferred tax asset for a net operating loss (NOL) carryforward, a similar tax loss, or a tax credit carryforward except when: (1) a NOL carryforward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date under the governing tax law to settle taxes that would result from the disallowance of the tax position; or (2) the entity does not intend to use the deferred tax asset for this purpose (provided that the tax law permits a choice). If either of these conditions exists, an entity should present an unrecognized tax benefit in the financial statements as a liability and should not net the unrecognized tax benefit with a deferred tax asset. ASU 2013-11 does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. ASU 2013-11 should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. We do not expect ASU 2013-11 to have an impact on our consolidated financial statements.

Critical Accounting Policies

Revenue Recognition. We currently generate revenue primarily from sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment from Cardinal Health’s national distribution center to another point of destination. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business.

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

We generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due. 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. 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 the fair value of financial instruments 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, 2013.

	Payments Due By Period					
Contractual Cash Obligations	Total	2014	2015	2016	2017	2018 and After
Purchase obligations	$1,663,990	$1,663,990	$—	$—	$—	$—
Capital lease obligation	8,357	3,039	3,039	2,279	—	—
Operating lease obligations	2,510,782	288,900	266,456	272,428	278,564	1,404,434

Principal and interest on long-term debt	34,548,208	7,515,088	11,488,610	15,544,510	—	—
Total contractual cash obligations	$38,731,337	$9,471,017	$11,758,105	$15,819,217	$278,564	$1,404,434

* 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, 2013, our $32.9 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, 2013, the interest rate on certain of our debt obligations was based on the U.S. prime rate. Based on the amount of our variable-rate borrowings at December 31, 2013, which totaled approximately $3.2 million, an immediate one percentage point increase in the U.S. prime rate would increase our annual interest expense by approximately $32,000. 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, 2013, 2012 and 2011, we recorded foreign currency transaction losses of approximately $8,000, $15,000 and $3,000, 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 our warrant liabilities is determined using various inputs and assumptions, the majority of which are defined and fixed by the warrant agreement, including the price of Company stock. As of December 31, 2013, we had approximately $7.7 million of derivative liabilities recorded on our balance sheet related to 3,169,015 Series JJ warrants. Due to the fixed inputs defined by the warrant agreement, a hypothetical 50% change in our stock price would have no effect on the value of our derivative liabilities.

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 14, 2014 are set forth at pages F-1 through F-29 attached hereto and incorporated herein by reference.

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, 2013. 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, 2013. 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 (1992). Based on our assessment we concluded that, as of December 31, 2013, 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 56.

Changes in Internal Control Over Financial Reporting

During the year ended December 31, 2013, 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.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Navidea Biopharmaceuticals, Inc.
Dublin, Ohio

We have audited Navidea Biopharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control – Integrated Framework (1992) 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, 2013, 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, 2013 and 2012, 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, 2013 and our report dated March 14, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Chicago, Illinois
March 14, 2014

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Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

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

Name	Age	Committee(s)
Peter F. Drake, Ph.D.	60	Audit; Compensation, Nominating and Governance (Chairman)
Brendan A. Ford	55	Audit (Chairman); Compensation, Nominating and Governance
Perry A. Karsen	58	—
Michael M. Goldberg, M.D.	55	—
Mark J. Pykett, V.M.D., Ph.D.	50	—
Eric K. Rowinsky, M.D.	57	—
Gordon A. Troup	60	Audit; Compensation, Nominating and Governance

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 2014 Annual Meeting:

Michael M. Goldberg, M.D. has served as a director of Navidea since November 2013. Dr. Goldberg has served as a Managing Partner of Montaur Capital Partners since January 2007. Dr. Goldberg served as the Chief Executive Officer of Emisphere Technologies, Inc., from August 1990 to January 16, 2007 and as its President from August 1990 to October 1995. He served as Vice President of The First Boston Corp., where he was a founding member of the Healthcare Banking Group. Dr. Goldberg served as Chairman of the Board of Directors of Emisphere Technologies, Inc., from November 1991 to January 2007. He has been a Director of ADVENTRX Pharmaceuticals Inc., Alliqua, Inc., and Urigen Pharmaceuticals, Inc. He currently serves as a Director of AngioLight, Inc., a privately-held company. Dr. Goldberg received a B.S. degree from Rensselaer Polytechnic Institute, an M.D. from Albany Medical College of Union University in 1982, and an M.B.A. from Columbia University Graduate School of Business in 1985.

Mark J. Pykett, V.M.D, Ph.D. currently serves as Chief Executive Officer of Navidea, joining the Company in 2010. He also served as Navidea’s President and CEO from April 2011 until May 2013. He has more than 17 years of experience in pharmaceutical industry executive management. Prior to joining Navidea as 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 has also held senior executive roles at several public and private biotechnology companies 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 received a B.A. degree from Amherst College, a V.M.D. and Ph.D. from the University of Pennsylvania, and an M.B.A. from Northeastern University, and completed post-doctoral fellowships at the University of Pennsylvania and Harvard University.

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 and The San Diego Museum of Art. Dr. Drake received his undergraduate degree from Bowdoin College, and his Ph.D. in neurobiology and biochemistry from Bryn Mawr College.

Perry A. Karsen has served as a director of Navidea since February 2014. Mr. Karsen has served as Chief Operations Officer of Celgene Corporation (Celgene) since July 2010 and as Executive Vice President and Chief Operations Officer of Celgene since February 2012, accountable for various operations functions, including corporate and business development, technical operations and Celgene's Cellular Therapeutics division, where he serves as Chief Executive Officer. Mr. Karsen served as President and Chief Executive Officer at Pearl Therapeutics, a privately-held biotechnology company, from February 2009 until July 2010. From 2004 to 2009, Mr. Karsen was Senior Vice President and Head of Worldwide Business Development for Celgene and was also responsible for emerging businesses as President, Asia/Pacific Region. Prior to his tenure with Celgene, Mr. Karsen held executive positions at Human Genome Sciences, Bristol-Myers Squibb, Genentech and Abbott Laboratories. In addition, Mr. Karsen served as a General Partner at Pequot Ventures. Mr. Karsen serves as a member of the Board of Directors of the

Biotechnology Industry Organization (BIO); a member of the Board of Directors of BayBio; and a member of the Board of Directors for the Life Sciences Foundation. In addition, Mr. Karsen is a member of the Board of Directors of Agios Pharmaceuticals. Mr. Karsen has a Masters of Management degree from Northwestern University's Kellogg Graduate School of Management, a Masters in Teaching of Biology from Duke University, and a B.S. in Biological Sciences from the University of Illinois, Urbana.

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.

Directors whose terms continue until the 2016 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. Dr. Rowinsky focuses on the development and registration of novel therapeutics in cancer and other indications. He is currently the Chief Medical Officer and Head of Research and Development at Stemline Therapeutics, Inc. Prior to joining Stemline in January 2012, Dr. Rowinsky was co-founder and Chief Executive Officer of Primrose Therapeutics, Inc., a start-up biotechnology company. From 2005 to 2010, Dr. Rowinsky was Executive Vice President and Chief Medical Officer of ImClone Systems, Inc., where he led the FDA approval of Erbitux® for head and neck and colorectal cancers. From 1996 to 2004, he served as the Head of Clinical Research and then Director of the Institute of Drug Development of the Cancer Research Center in San Antonio and Clinical Professor of Medicine at the University of Texas Health Science Center at San Antonio. From 1988 to 1996, Dr. Rowinsky was an Associate Professor of Oncology at the Johns Hopkins University School of Medicine. During his tenure in academia, he was integrally involved in pivotal clinical and preclinical investigations that led to the development of numerous cancer therapeutics, including paclitaxel, docetaxel, topotecan, irinotecan, erlotinib, gefitinib, and temsirolimus among others. Dr. Rowinsky is currently an Adjunct Professor of Medicine at New York University School of Medicine and he sits on the Board of Directors of the following publically traded biotechnology companies: Navidea, Coronado Biosciences and BiogenIdec. He received his M.D. from Vanderbilt University School of Medicine and completed his residency in internal medicine at the University of California, San Diego and a fellowship in medical oncology at Johns Hopkins Oncology Center. He holds a B.A. from New York University.

Executive Officers

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

Name	Age	Position
Frederick O. Cope, Ph.D.	67	Senior Vice President and Chief Scientific Officer
Brent L. Larson	50	Executive Vice President; Chief Financial Officer; Treasurer and Secretary

William J. Regan	62	Senior Vice President, Global Regulatory Affairs and Quality
Cornelia B. Reininger, M.D., Ph.D.	61	Senior Vice President and Chief Medical Officer
Thomas H. Tulip, Ph.D.	61	President and Chief Business Officer

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Frederick O. Cope, Ph.D., F.A.C.N., C.N.S., has served as Chief Scientific Officer of Navidea since May of 2013, 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 Executive Vice President of Navidea since May 2013, as Senior Vice President from July 2010 to April 2013, 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 Affairs and Quality of Navidea since February 2014 and as Senior Vice President, Global Regulatory Strategy of Navidea from October 2012 to January 2014. 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.

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Thomas H. Tulip, Ph.D., has served as President and Chief Business Officer of Navidea since May 2013, and as Executive Vice President from June 2011 to April 2013. 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, 2013, except for: Peter F. Drake, Ph.D., Brendan A. Ford, Jess Emery Jones, M.D., Eric K. Rowinsky, M.D. and Gordon A. Troup, who each had one late Form 4 filing related to a February 2013 grant of restricted stock.

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.navidea.com. The code of business conduct and ethics may also be obtained free of charge by writing to Navidea Biopharmaceuticals, Inc., Attn: Chief Financial Officer, 5600 Blazer Parkway, Suite 200, 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 19 meetings in the fiscal year ended December 31, 2013, 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, with the exception of Jess Emery Jones, M.D., who resigned from the Board on July 9, 2013. 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 2013 Annual Meeting of Stockholders in person, except for Jess Emery Jones, M.D.

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., 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, 2013. 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 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 Gordon A. Troup. The CNG Committee held five meeting in the fiscal year ended December 31, 2013 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.

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 while taking into account current market conditions and Company performance. This allows us to attract, hire, reward and retain senior executives who 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 at least annually. 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 our 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 or 2013. 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 (Pearl Meyer) 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 2013. No conflict of interest exists that would prevent Pearl Meyer from serving as independent consultant to the CNG Committee.

For fiscal 2013, 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, 2014 by an annualized rate of 3.0%, the expected pay increase in 2013 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 2013, the CNG Committee noted that our overall executive compensation was, on average, between the 25th and 50th percentile for an established peer group of companies.

Peer Group Companies. In addition to the above survey analysis, in 2013 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.

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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:

OncoGenex Pharmaceuticals Inc.
ArQule Inc.
Progenics Pharmaceuticals Inc.
Threshold Pharmaceuticals Inc.
Curis Inc.
Hyperion Therapeutics Inc.
Keryx Biopharmaceuticals Inc.
lmmunomedics Inc.
Targacept Inc.
EXACT Sciences Corp.
Cell Therapeutics Inc.
Rigel Pharmaceuticals Inc.
ZIOPHARM Oncology Inc.
Delcath Systems Inc.
TG Therapeutics Inc.
GTx 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 2013 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 2013, 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 2013 compared to the approved salaries for fiscal 2012:

Named Executive Officer	Fiscal 2013 Base Salary	Fiscal 2012 Base Salary	Increase [a]	
Mark J. Pykett, V.M.D., Ph.D.[b]	$437,750	$425,000	3.0	%
Frederick O. Cope, Ph.D. [b]	279,130	271,000	3.0	%
Brent L. Larson[b]	279,575	265,000	5.5	%

Cornelia B. Reininger, M.D., Ph.D. [c]	300,000	—	—	%
Thomas H. Tulip, Ph.D. (b)	339,625	325,000	4.5	%

(a) 2013 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) The Named Executive Officer's salary was increased effective May 1, 2013. The amount shown for fiscal 2013 is the approved annual salary of the Named Executive Officer in effect at the end of 2013. The actual amount paid to the Named Executive Officer during fiscal 2013 is shown under “Salary” in the Summary Compensation table below.

(c) Dr. Reininger commenced employment with the Company effective November 1, 2012.

The CNG Committee has approved the following base salaries for fiscal 2014: Dr. Pykett, $399,000; Dr. Cope, $279,130; Mr. Larson, $260,000; Dr. Reininger, $300,000; and Dr. Tulip, $314,000.

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 in part 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 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 was a function of the designated target bonus amount and certain business performance objectives, weighted as a percentage of the total target amount. The business performance objectives established for fiscal 2013 were as follows:

- Approval of the Company's Lymphoseek® (technetium Tc 99m tilmanocept) Injection product by the United States Food and Drug Administration (FDA), initiation of the commercial launch of Lymphoseek in the United States, and achievement of a targeted amount of revenues from sales, subject to a maximum 35% reduction of bonus if not achieved.
- Submission of a supplemental New Drug Application (sNDA) for Lymphoseek to the FDA, subject to a 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 disease, subject to a 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 a maximum 10% reduction of bonus if not achieved.

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

For the Named Executive Officers, the CNG Committee established the following cash bonus targets for fiscal 2013:

Named Executive Officer	Target Cash Bonus (% of Salary)	Target Cash Bonus ($ Amount)
Mark J. Pykett, V.M.D., Ph.D.	50.0 %	$212,500
Frederick O. Cope, Ph.D.	25.0 %	67,750
Brent L. Larson	27.5 %	72,875
Cornelia B. Reininger, M.D., Ph.D.	30.0 %	90,000
Thomas H. Tulip, Ph.D.	35.0 %	113,750

In January 2014, the CNG Committee determined the extent to which the Company's goals were achieved during 2013. With respect to the first objective, the Company obtained FDA approval for Lymphoseek and the product was commercially launched in the United States, however the Company did not realize the targeted amount of revenues from sales, therefore the Committee concluded that the goal was partially achieved, resulting in a 20% reduction in the target bonus amount. With regard to the second objective, the Committee concluded that the submission of a sNDA for Lymphoseek to the FDA in December 2013 evidenced the successful achievement of that goal. With regard to the third objective, the Committee determined that the initiation of enrollment in a global Phase 3 clinical trial of NAV4694 in June 2013 evidenced the successful achievement of that goal. With regard to the fourth objective, the Committee concluded that the initiation of the pivotal Phase 3 clinical study of NAV5001 in December 2013 constituted the successful achievement of that goal. With respect to the discretionary portion of the total bonus opportunity, the Committee concluded that this component would be subject to a 10% reduction of bonuses for non-executives, with the discretionary portion of executive bonuses to be determined on a case-by-case basis consistent with management's recommendations. 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 2014, are shown under "Non-Equity Incentive Plan Compensation" in the Summary Compensation table below.

Also in January 2014, the CNG Committee established the fiscal 2014 targets and performance measures for all Company employees. For fiscal 2014, the cash bonus for each executive officer will be a function of the designated target bonus amount and certain business performance objectives, weighted as a percentage of the total target amount. The business performance objectives established for fiscal 2014 are as follows:

- Achievement of various development and commercial goals for the Company's Lymphoseek product, including:
  - generation of specified revenue amounts derived directly from Lymphoseek during fiscal 2014, subject to a maximum 40% reduction of bonus if not achieved;
  - approval of the sNDA for Lymphoseek for head and neck cancer, subject to a maximum 5% reduction of bonus if not achieved; and
  - initiation of ex-U.S. commercial launch activities in select countries, subject to a maximum 5% reduction of bonus if not achieved.
- Achievement of a specified percentage of the total target enrollment in the Company's NAV4-02 Phase 3 trial for NAV4694, subject to a maximum 10 % reduction of bonus if not achieved.
- Realization of a specified amount in revenue from 'business development' sources such as in-licensing or partnering milestone payments, subject to a maximum 15% reduction of bonus if not achieved.
- Commencement of a Phase 1 or later stage clinical study for a Manocept platform product candidate, subject to a maximum 5% reduction of bonus if not achieved.
- Discretionary bonus, equal to 20% of the total bonus objective.

The CNG Committee has approved the following target cash bonus amounts for the Named Executive Officers for fiscal 2014: Dr. Pykett, $199,500; Dr. Cope, $69,783; Mr. Larson, $71,500; Dr. Reininger, $90,000; and Dr. Tulip, $109,900.

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 full-time 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 15, 2013, the Company granted options to purchase shares of common stock of the Company to all full-time Company employees, including the Named Executive Officers. The stock options have an exercise price of $3.08, 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 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 agreement all stock options that have not vested at the effective date of the Named Executive Officer's termination shall immediately vest and become exercisable. The following number of options was granted to each Named Executive Officer: Dr. Pykett, 304,000; Dr. Cope, 145,000; Mr. Larson, 142,000; Dr. Reininger, 120,000; and Dr. Tulip, 174,000.

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) 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 up to 5% of salary in the form of our common stock). 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 senior 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 a senior executive officer is concurrently or subsequently terminated:

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

then, the senior 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 a 36-month employment agreement effective through April 14, 2014. 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. Effective May 1, 2013, Dr. Pykett's annual base salary was increased to $437,750. For the calendar year ending December 31, 2013, the CNG Committee determined that the maximum bonus payment to Dr. Pykett would be $212,500.

Frederick O. Cope, Ph.D. Dr. Cope is employed under a 24-month employment agreement effective through December 31, 2014. 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. Effective May 1, 2013, Dr. Cope's annual base salary was increased to $279,130. For the calendar year ending December 31, 2013, the CNG Committee determined that the maximum bonus payment to Dr. Cope would be $67,750.

Brent L. Larson. Mr. Larson is employed under a 24-month employment agreement effective through December 31, 2014. 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. Effective May 1, 2013, Mr. Larson’s annual base salary was increased to $279,575. For the calendar year ending December 31, 2013, the CNG Committee determined that the maximum bonus payment to Mr. Larson would be $72,875.

Cornelia B. Reininger, M.D., Ph.D. Dr. Reininger is employed under a 17-month employment agreement effective through March 31, 2014. The employment agreement provides for an annual base salary of $300,000. For the calendar year ending December 31, 2013, the CNG Committee determined that the maximum bonus payment to Dr. Reininger would be $90,000.

Thomas H. Tulip, Ph.D. Dr. Tulip is employed under a 24-month employment agreement effective through May 31, 2014. The employment agreement provides for an annual base salary of $325,000. Effective May 1, 2013, Dr. Tulip's annual base salary was increased to $339,625. For the calendar year ending December 31, 2013, the CNG Committee determined that the maximum bonus payment to Dr. Tulip would be $113,750.

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, 2013 and a stock price of $2.07, our closing stock price on December 31, 2013.

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)	$—	$—	$—	$—	$385,462	$468,750	$937,500
Disability supplement (b)	—	—	—	216,475	—	—	—
Paid time off (c)	8,418	8,418	8,418	8,418	8,418	8,418	8,418
2013 401(k) match (d)	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Continuation of benefits (e)	—	—	25,275	25,275	—	37,912	25,275
Stock option vesting acceleration (f)	—	—	—	—	—	—	—
Restricted stock vesting acceleration (g)	—	—	—	—	—	413,800	775,875
Total	$13,418	$13,418	$38,693	$255,168	$398,880	$933,880	$1,752,068

(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, 2013.

(d) Amount represents the value of 1,843 shares of Company stock which was accrued during 2013 as the Company's 401(k) matching contribution but was unissued as of December 31, 2013.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2013, 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, 2013.

(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 $2.07, the closing price of the Company's stock on December 31, 2013, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.07, the closing price of the Company's stock on December 31, 2013.

(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.

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)	—	—	—	137,165	—	—	—
Paid time off (c)	5,368	5,368	5,368	5,368	5,368	5,368	5,368
2013 401(k) match (d)	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Continuation of benefits (e)	—	—	17,854	17,854	—	17,854	17,854
Stock option vesting acceleration (f)	—	—	—	—	5,100	5,100	5,100
Restricted stock vesting acceleration (g)	—	—	—	—	—	—	103,450
Total	$10,368	$10,368	$28,222	$165,387	$260,468	$278,322	$504,272

(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 40 hours of accrued but unused vacation time as of December 31, 2013.

(d) Amount represents the value of 1,843 shares of Company stock which was accrued during 2013 as the Company's 401(k) matching contribution but was unissued as of December 31, 2013.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2013.

(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 $2.07, the closing price of the Company's stock on December 31, 2013, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.07, the closing price of the Company's stock on December 31, 2013.

(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)	—	—	—	137,388	—	—	—
Paid time off (c)	5,376	5,376	5,376	5,376	5,376	5,376	5,376
2013 401(k) match (d)	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Continuation of benefits (e)	—	—	25,275	25,275	—	25,275	25,275
Stock option vesting acceleration (f)	—	—	—	—	4,038	4,038	4,038
Total	$10,376	$10,376	$35,651	$173,039	$221,414	$246,689	$350,189

(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, 2013.

(d) Amount represents the value of 1,843 shares of Company stock which was accrued during 2013 as the Company's 401(k) matching contribution but was unissued as of December 31, 2013.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2013.

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

(f) represents the value of the stock at $2.07, the closing price of the Company's stock on December 31, 2013, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.07, the closing price of the Company's stock on December 31, 2013.

Cornelia B. Reininger, M.D., Ph.D.

	For Cause	Resignation	Death	Disability	End of Term	Without Cause	Change in Control
Cash payments:							
Severance (a)	$—	$—	$—	$—	$300,000	$300,000	$450,000
Disability supplement (b)	—	—	—	147,600	—	—	—
Paid time off (c)	3,462	3,462	3,462	3,462	3,462	3,462	3,462
2013 401(k) match (d)	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Continuation of benefits (e)	—	—	11,325	11,325	—	11,325	11,325
Stock option vesting acceleration (f)	—	—	—	—	—	—	—
Total	$8,462	$8,462	$19,787	$167,387	$308,462	$319,787	$469,787

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

(b) During the first 6 months of disability, the Company will supplement disability insurance payments to Dr. Reininger 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 24 hours of accrued but unused vacation time as of December 31, 2013.

(d) Amount represents the value of 1,855 shares of Company stock which was accrued during 2013 as the Company's 401(k) matching contribution but was unissued as of December 31, 2013.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2013.

Pursuant to Dr. Reininger'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.

(f) Amount represents the value of the stock at $2.07, the closing price of the Company's stock on December 31, 2013, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.07, the closing price of the Company's stock on December 31, 2013.

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)	—	—	—	167,413	—	—	—
Paid time off (c)	6,531	6,531	6,531	6,531	6,531	6,531	6,531
2013 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	$11,531	$11,531	$11,531	$178,944	$336,531	$336,531	$499,031

(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, 2013.

(d) Amount represents the value of 1,843 shares of Company stock which was accrued during 2013 as the Company's 401(k) matching contribution but was unissued as of December 31, 2013.

(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 $2.07, the closing price of the Company's stock on December 31, 2013, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $2.07, the closing price of the Company's stock on December 31, 2013.

(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
Gordon A. Troup

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 Gordon A. Troup, 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, 2013, or at any other time, an officer or employee of the Company.

No director who served on the CNG Committee during 2013 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 an 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 2013.

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 2013

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.	2013	$433,500	$—	$557,448	$127,500	$6,749	$1,125,197
Chief Executive Officer	2012	425,000	983,700	385,462	140,250	13,808	1,948,220
	2011	363,249	201,450	—	175,867	4,788	745,354
Frederick O. Cope, Ph.D.	2013	$276,420	$—	$265,888	$50,813	$6,179	$599,300
Senior Vice President and	2012	271,000	—	244,768	55,043	11,114	581,925
Chief Scientific Officer	2011	252,342	—	—	63,375	10,396	326,113
Brent L. Larson	2013	$274,717	$—	$260,387	$51,013	$6,847	$592,964
Executive Vice President and	2012	265,000	—	169,603	49,555	11,404	495,562
Chief Financial Officer	2011	222,637	—	—	43,875	8,450	274,962
Cornelia B. Reininger, M.D., Ph.D. (e)	2013	$300,000	$—	$220,045	$67,500	$98,087	$685,632
Senior Vice President and	2012	—	—	—	—	—	—
Chief Medical Officer	2011	—	—	—	—	—	—
Thomas H. Tulip, Ph.D. (f)	2013	$334,750	$—	$319,066	$71,094	$6,000	$730,910
President and	2012	314,583	—	314,151	75,075	9,615	713,424
Chief Business Officer	2011	175,000	394,320	346,842	60,023	5,708	981,893

(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 2013, 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. Reininger commenced employment with the Company effective November 1, 2012.

(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 2013

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	Other		Total All Other Compensation
Mark J. Pykett, V.M.D., Ph.D.	2013	$—	$1,749	$5,000	$—		$6,749
	2012	7,212	1,596	5,000	—		13,808
	2011	—	1,019	3,769	—		4,788
Frederick O. Cope, Ph.D.	2013	$—	$1,179	$5,000	$—		$6,179
	2012	5,096	1,018	5,000	—		11,114
	2011	4,818	678	4,900	—		10,396
Brent L. Larson	2013	$—	$1,847	$5,000	$—		$6,847
	2012	4,808	1,596	5,000	—		11,404
	2011	2,531	1,019	4,900	—		8,450
Cornelia B. Reininger, M.D., Ph.D.	2013	$—	$112	$5,000	$92,975	(d)	$98,087
	2012	—	—	—	—		—
	2011	—	—	—	—		—
Thomas H. Tulip, Ph.D.	2013	$—	$—	$5,000	$1,000	(e)	$6,000
	2012	4,615	—	5,000	—		9,615
	2011	—	2,807	2,901	—		5,708

(a) Amount represents payment for unused vacation time in excess of the amount eligible for rollover in a fiscal year. 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) Amount represents Dr. Reininger's moving expenses to relocate from Germany to the U.S. of $58,827, reimbursement of additional income taxes on the value of the moving expenses of $12,857, immigration-related legal fees of $11,953 and car allowance payments totaling $9,338.

(e) Amount represents Dr. Tulip's additional bonus paid for non-participation in the Company’s medical, dental, and vision plans.

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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 2013. 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 2013

Named Executive Officer	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards (a)		Estimated Future Payouts Under Equity Incentive Plan Awards		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	
		Threshold	Maximum	Threshold	Maximum					
Mark J. Pykett, V.M.D., Ph.D.	N/A	$—	$212,500	—	—	—	—	$—	$—	(a)
	2/15/2013	$—	$—	—	—	—	304,000	$3.08	$557,448	(b)
Frederick O. Cope, Ph.D.	N/A	$—	$67,750	—	—	—	—	$—	$—	(a)
	2/15/2013	$—	$—	—	—	—	145,000	$3.08	$265,888	(b)
Brent L. Larson	N/A	$—	$72,875	—	—	—	—	$—	$—	(a)
	2/15/2013	$—	$—	—	—	—	142,000	$3.08	$260,387	(b)
Cornelia B. Reininger, M.D., Ph.D.	N/A	$—	$90,000	—	—	—	—	$—	$—	(a)
	2/15/2013	$—	$—	—	—	—	120,000	$3.08	$220,045	(b)
Thomas H. Tulip, Ph.D.	N/A	$—	$113,750	—	—	—	—	—	$—	(a)
	2/15/2013	$—	$—	—	—	—	174,000	$3.08	$319,066	(b)

(a) The threshold amount reflects the fact that no cash bonus awards would have been payable if none of the specified business performance objectives were achieved. The maximum amount reflects the target cash bonus awards payable if all of the specified business performance objectives are achieved. For actual cash bonus award amounts, see the “Non-Equity Incentive Plan Compensation” column in the Summary Compensation table above.

(b) 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, 2013.

Outstanding Equity Awards Table at Fiscal 2013 Year-End

	Option Awards					Stock Awards				
								Equity Incentive Plan Awards		
Named Executive Officer	Number of Securities Underlying Unexercised Options (#) Exercisable	Unexercisable	Option Exercise Price	Option Expiration Date	Note	Number of Shares of Stock that Have Not Vested	Market Value of Shares of Stock that Have Not Vested	Number of Unearned Shares	Market Value of Unearned Shares (u)	Note
Mark J. Pykett, V.M.D., Ph.D.	200,000	—	$1.70	11/12/2020	(j)			175,000	$362,250	(r)
	62,500	137,500	$3.28	2/17/2022	(n)	200,000	$414,000			(t)
	—	304,000	$3.08	2/15/2023	(p)					
Frederick O. Cope, Ph.D.	50,000	—	$0.65	2/16/2019	(h)			50,000	$103,500	(q)
	75,000	—	$1.10	10/30/2019	(i)					
	90,000	30,000	$1.90	12/21/2020	(k)					
	31,750	95,250	$3.28	2/17/2022	(m)					
	—	145,000	$3.08	2/15/2023	(p)					
Brent L. Larson	70,000	—	$0.30	1/7/2014	(a)					
	50,000	—	$0.49	7/28/2014	(b)					
	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)					
	71,250	23,750	$1.90	12/21/2020	(k)					
	22,000	66,000	$3.28	2/17/2022	(m)					
	—	142,000	$3.08	2/15/2023	(p)					
Cornelia B. Reininger, M.D., Ph.D.	22,000	66,000	$2.85	11/1/2022	(o)					
	—	120,000	$3.08	2/15/2023	(p)					
Thomas H. Tulip,	55,000	55,000	$4.93	6/1/2021	(l)			60,000	$124,200	(s)

Ph.D.	40,750	122,250	$3.28	2/17/2022	(m)
	—	174,000	$3.08	2/15/2023	(p)

(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) Options were granted 2/17/2012; 62,500 options will vest on each of the first three anniversaries of the date of grant, and 12,500 options will vest on the fourth anniversary of the date of grant.

(o) Options were granted 11/1/2012 and vest as to one-fourth on each of the first four anniversaries of the date of grant.

(p) Options were granted 2/15/2013 and vest as to one-fourth on each of the first four anniversaries of the date of grant.

(q) Restricted shares granted February 16, 2009. Pursuant to the terms of the restricted stock agreement between the Company and Dr. Cope, the restricted shares will vest upon the commencement of patient enrollment in a Phase 3 clinical trial in humans of NAV1800. 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.

(r) Restricted shares granted November 15, 2010. Pursuant to the terms of the restricted stock agreement between the Company and Dr. Pykett, the restricted shares will vest upon the approval of a NDA for a NAV1800 technology product by the FDA or the approval of marketing authorization for a NAV1800 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.

(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, 100,000 shares vest on February 17, 2013; 100,000 shares vest on March 17, 2014; and 100,000 shares vest on February 17, 2015. 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, 2013, 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, 2013, was $2.07.

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 2013.

Options Exercised and Stock Vested Table for Fiscal 2013

	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.	—	—	275,000	$860,725	(b)(c)
Frederick O. Cope, Ph.D.	—	—	125,000	$394,875	(d)

Brent L. Larson	—	—	125,000	$394,875	(e)
Cornelia B. Reininger, M.D., Ph.D.	—	—	—	—	
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.

(b) On February 17, 2013, 100,000 shares of Dr. Pykett’s restricted stock vested in accordance with the terms of his restricted stock agreement. The market price of the stock on the last trading day prior to the vesting date was $3.08 per share.

(c) On March 13, 2013, the FDA approval of Lymphoseek caused 175,000 shares of Dr. Pykett's restricted stock to vest in accordance with the terms of his restricted stock agreement. The market price of the stock on the vesting date was $3.16 per share.

(d) On March 13, 2013, the FDA approval of Lymphoseek caused 125,000 shares of Dr. Cope's restricted stock to vest in accordance with the terms of his restricted stock agreement. The market price of the stock on the vesting date was $3.16 per share.

(e) On March 13, 2013, the FDA approval of Lymphoseek caused 125,000 shares of Mr. Larson's restricted stock to vest in accordance with the terms of his restricted stock agreement. The market price of the stock on the vesting date was $3.16 per share.

Compensation of Non-Employee Directors

Each non-employee director received an annual cash retainer of $25,000 and earned an additional $2,500 per board meeting attended in person or $500 per telephonic board meeting during the fiscal year ended December 31, 2013. 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 2013. 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 2013.

Each non-employee director also received 12,250 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. Fourth 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, 2014 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 Navidea 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, 2013.

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.	$58,000	$—	$35,635	$—	$93,635
Brendan A. Ford	61,500	—	35,635	—	97,135
Michael M. Goldberg, M.D. (f)	4,329	—	18,363	—	22,692
Jess Emery Jones, M.D.(g)	22,111	—	35,635	—	57,746
Eric K. Rowinsky, M.D.	38,500	—	35,635	—	74,135
Gordon A. Troup	71,500	—	35,635	—	107,135

(a) Amount represents fees earned during the fiscal year ended December 31, 2013 (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, 2013, 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, 2013, the non-employee directors were issued an aggregate of 73,500 shares of restricted stock which vest as to 100% of the shares on the first anniversary of the date of grant. At December 31, 2013, the non-employee directors held an aggregate of 129,250 shares of unvested restricted stock. Messrs. Ford and Troup and Drs. Rowinsky and Drake each held 29,250 shares of unvested restricted stock, and Dr. Goldberg held 12,250 shares of unvested restricted stock.

(f) Dr. Goldberg was appointed to the board on November 13, 2013.

(g) Dr. Jones resigned from our Board of Directors effective July 9, 2013.

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, 2013, 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)	4,866,602	$2.38	1,681,407
Equity compensation plans not approved by security holders	—	—	—
Total	4,866,602	$2.38	1,681,407

(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, 2014, 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 (**)	
Frederick O. Cope, Ph.D.	414,201	(a)	—	(m)
Peter F. Drake, Ph.D.	39,250	(b)	—	(m)
Brendan A. Ford	139,250	(b)	—	(m)
Michael M. Goldberg, M.D.	147,991	(c)	—	(m)
Perry A. Karsen	—	(d)	—	(m)
Brent L. Larson	906,963	(e)	—	(m)

Mark J. Pykett, V.M.D., Ph.D.	707,625	(f)	—	(m)
Cornelia B. Reininger, M.D., Ph.D.	52,000	(g)	—	(m)
Eric K. Rowinsky, M.D.	208,014	(h)	—	(m)
Gordon A. Troup	166,250	(i)	—	(m)
Thomas H. Tulip, Ph.D.	227,593	(j)	—	(m)
All directors and executive officers as a group (12 persons)	3,101,137	(k)(n)	2.0	%
Platinum-Montaur Life Sciences, LLC	14,185,069	(l)	9.99	%

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

(**) Percent of class is calculated on the basis of the number of shares outstanding on February 28, 2014, plus the number of shares the person has the right to acquire within 60 days of February 28, 2014.

(a) This amount includes 314,750 shares issuable upon exercise of options which are exercisable within 60 days and 8,637 shares in Dr. Cope's account in the 401(k) Plan, but it does not include 50,000 shares of unvested restricted stock and 335,250 shares issuable upon exercise of options which are not exercisable within 60 days.

(b) This amount does not include 37,000 shares of unvested restricted stock.

(c) This amount does not include 32,250 shares of unvested restricted stock.

(d) This amount does not include 20,000 shares of unvested restricted stock.

(e) This amount includes 490,750 shares issuable upon exercise of options which are exercisable within 60 days and 93,217 shares in Mr. Larson's account in the 401(k) Plan, but it does not include 298,250 shares issuable upon exercise of options which are not exercisable within 60 days.

(f) This amount includes 401,000 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 2,851 shares in Dr. Pykett's account in the 401(k) Plan, but it does not include 275,000 shares of unvested restricted stock and 611,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(g) This amount includes 52,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 299,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(h) This amount includes 73,764 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 37,000 shares of unvested restricted stock.

(i) This amount includes 20,000 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 37,000 shares of unvested restricted stock.

(j) This amount includes 180,000 shares issuable upon exercise of options which are exercisable within 60 days and 2,593 shares in Dr. Tulip's account in the 401(k) Plan, but it does not include 60,000 shares of unvested restricted stock and 417,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(k) This amount includes 1,619,264 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 107,298 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 605,250 shares of unvested restricted stock and 2,232,500 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 364,980 shares of common stock. The 12 persons referenced in this disclosure include each director and named executive officer listed in the table as well as one additional executive officer who is not a named executive officer.

(l) Based on information provided to Navidea as of February 11, 2014. The number of shares beneficially owned by Platinum-Montaur Life Sciences, LLC (Platinum), 152 W. 57th Street, 54th Floor, New York, NY 10019, does not include 11,127,810 shares of common stock issuable upon conversion of 3,403 shares of Series B Convertible Preferred Stock. The Certificate of Designation of the Preferred Stock provides that the holder of shares of the Preferred Stock may not convert any of the Preferred Stock to the extent that such conversion or exercise would result in the holder and its affiliates together beneficially owning more than 9.99% of the outstanding shares of common stock, except on 61 days' prior written notice to Navidea that the holder waives such limitation.

(m) Less than one percent.

(n) The address of all directors and executive officers is c/o Navidea Biopharmaceuticals, Inc., 5600 Blazer Parkway, Suite 200, Dublin, OH 43017.

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.

Effective November 13, 2013, the Company appointed Michael M. Goldberg, M.D., to serve on its Board of Directors. At the time of his appointment, Dr. Goldberg was Portfolio Manager of Platinum-Montaur Life Sciences, LLC, a Delaware limited liability company (Platinum).

Dr. Goldberg accepted his appointment to serve on the Company's Board of Directors in accordance with the provisions of a Director Agreement, dated November 13, 2013, between the Company and Dr. Goldberg. Pursuant to the terms of the Director Agreement, Dr. Goldberg has acknowledged and agreed that, for as long as he is a member of the Board of Directors, he will not, directly or indirectly, have any power to direct or cause the direction of the voting or disposition of any securities of the Company directly or beneficially owned by Platinum or its affiliates. Dr. Goldberg has advised the Company that he is in the process of completing his withdrawal from any ownership or management position with Platinum, but he has not advised the Company of the terms or timing of such separation.

SEC disclosure rules regarding transactions with related persons require the Company to provide information about transactions with Dr. Goldberg as a related person, even though Dr. Goldberg was not a related person at the time the Company entered into the transactions described below.

As of February 28, 2014, Platinum beneficially owned approximately 14,185,069 shares of our common stock, excluding 11,127,810 shares of our common stock issuable upon the conversion of 3,403 shares of Series B Convertible Preferred Stock.

In June 2013, in connection with entering a Loan and Security Agreement (the GECC/MidCap Loan Agreement) with General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap), providing for a loan to the Company of $25 million, the Company and Platinum entered into an amendment (the First Platinum Amendment) to a loan agreement between the Company and Platinum (the Platinum Loan Agreement). The Company, Platinum, and GECC/MidCap also entered into a Subordination Agreement (the Subordination Agreement), providing for subordination of the Company's indebtedness under the Platinum Loan Agreement to the Company's indebtedness under the GECC/MidCap Loan Agreement, among other customary terms and conditions.

In connection with the execution of the First Platinum Amendment, the Company delivered an amended and restated promissory note (the First Amended Platinum Note) to Platinum, which amended and restated the original promissory note, issued to Platinum, in the principal amount of up to $35 million. The First Amended Platinum Note adjusted the interest rate 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 GECC/MidCap Loan Agreement plus 0.125% (effective interest rate at February 28, 2014, was 10%).

In addition, the First Platinum Amendment granted Platinum the right, at Platinum's option, to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draws (the Conversion Amount), beginning on a date two years from the date the draw was advanced, into the number of shares of the Company's common stock computed by dividing the Conversion Amount by a conversion price equal to the lesser of (i) 90% of the lowest VWAP for the 10 trading days preceding the date of such conversion request, or (ii) the average VWAP for the 10 trading days preceding the date of such conversion request. The First Platinum Amendment also provided a conversion right on the same terms with respect to the amount of any mandatory repayment due following the Company achieving $2,000,000 in cumulative revenues from sales or licensing of Lymphoseek. The conversion option applies to the Conversion Amount if the Company is prohibited from making such prepayment under the terms of the Subordination Agreement.

Also in connection with the First Platinum Amendment, the Company and Platinum entered into a Warrant Exercise Agreement, pursuant to which Platinum exercised its Series X Warrant and Series AA Warrant for 2,364.9 shares of the Company's Series B Convertible Preferred Stock, which are convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share). These warrants were exercised on a cashless basis by canceling a portion of the indebtedness outstanding under the Platinum Loan Agreement equal to $4,781,333, the aggregate exercise price of the warrants.

In March 2014, in connection with entering into a Loan and Security Agreement (the Oxford Loan Agreement) with Oxford Finance LLC (Oxford), providing for a loan to the Company of $30 million, we entered into a second amendment to the Platinum Loan Agreement (the Second Platinum Amendment). Concurrent with the execution of the Second Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the Second Amended Platinum Note) to Platinum, which amended and restated the First Amended Platinum Note. The Second Amended Platinum Note adjusted the interest rate to the greater of (i) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (ii) 10.0%, and (iii) the highest rate of interest then payable by the Company pursuant to the Oxford Loan Agreement plus 0.125%. Navidea, Platinum, and Oxford also entered into a Subordination Agreement, providing for subordination of the Company’s indebtedness under the Platinum Loan Agreement to the Company’s indebtedness under the Oxford Loan Agreement, among other customary terms and conditions.

During 2013, the largest aggregate amount of principal outstanding under the Platinum credit facility was $8 million, and as of February 28, 2014, the amount of principal outstanding was $3.2 million. During 2013, the Company extinguished $4.8 million of principal through a non-cash Warrant Exercise Agreement (discussed above) and $468,000 of interest at a rate of 10% under the Platinum credit facility.

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, Karsen and Troup, and Drs. Drake and Goldberg, meet the independence requirements. Dr. Jones also met the independence requirements until his resignation from the Board.

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 2013 fiscal year, the audit of the Company's internal control over financial reporting as of December 31, 2013, the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2013 fiscal year and consulting services related to certain debt and equity instruments during the 2013 fiscal year were $227,075 (including direct engagement expenses).

The aggregate fees 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).

Audit-Related Fees. No fees were billed by BDO USA, LLP for audit-related services for the 2013 or 2012 fiscal years.

Tax Fees. No fees were billed by BDO USA, LLP for tax-related services for the 2013 fiscal year. The aggregate fees 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).

All Other Fees. No fees were billed by BDO USA, LLP for services other than the audit, audit-related and tax services for the 2013 or 2012 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.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this report:

(1) The following Financial Statements are included in this Annual Report on Form 10-K on the pages indicated below:

(2) Financial statement schedules have been omitted because either they are not required or are not applicable or because the information required to be set forth therein is not material.

(3) Exhibits:

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, January 5, 2012, and June 26, 2013).*
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, July 26, 2007, and November 7, 2013 (filed as Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed November 12, 2013, and incorporated herein by reference).
4.1	Amended and Restated 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 26, 2013).

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 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).
10.13	Navidea Biopharmaceuticals, Inc. 2012 Cash Bonus Plan (incorporated by reference to the Company's Current Report on Form 8-K filed April 13, 2012). ^
10.14	Navidea Biopharmaceuticals, Inc. 2013 Cash Bonus Plan (incorporated by reference to the Company's Current Report on Form 8-K filed February 27, 2013). ^
10.15	Navidea Biopharmaceuticals, Inc. 2014 Cash Bonus Plan (incorporated by reference to the Company's Current Report on Form 8-K filed February 3, 2014). ^
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).
10.2	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	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).
10.30	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).
10.31	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).
10.32	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).

10.33	Amendment to Loan Agreement, dated June 25, 2013, between Navidea Biopharmaceuticals, Inc. and Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed June 28, 2013).
10.34	Second Amendment to Loan Agreement, dated March 4, 2014, between Navidea Biopharmaceuticals, Inc. and Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed March 7, 2014).
10.35	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).
10.36	Amended and Restated Promissory Note, dated June 25, 2013, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed June 28, 2013).
10.37	Second Amended and Restated Promissory Note, dated March 4, 2014, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed March 7, 2014).
10.38	Warrant Exercise Agreement, dated June 25, 2013, between Navidea Biopharmaceuticals, Inc. and Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed June 28, 2013).

10.39	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).
10.40	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).
10.41	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).
10.42	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).
10.43	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).
10.44	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).
10.45	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).
10.46	Securities Purchase Agreement, dated September 24, 2013, by and between the Company and the Crede CG III, Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 24, 2013).
10.47	Placement Agent Agreement, dated September 19, 2013, by and between the Company and JMP Securities LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 24, 2013).
10.48	Director Agreement, dated November 13, 2013, by and between Navidea Biopharmaceuticals, Inc. and Michael M. Goldberg, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 19, 2013).
10.49	Manufacturing Services Agreement, dated September 9, 2013, by and between Navidea Biopharmaceuticals, Inc. and OSO BioPharmaceuticals Manufacturing, LLC (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 September 12, 2013).
10.5	Office Lease, dated August 29, 2013, by and between Navidea Biopharmaceuticals, Inc. and BRE/COH OH LLC (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 September 5, 2013)
10.51	Manufacturing Services Agreement, dated August 16, 2013, by and between Navidea Biopharmaceuticals, Inc. and PETNET Solutions, Inc. (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 22, 2013).
10.52	Loan and Security Agreement, dated June 25, 2013, among General Electric Capital Corporation as agent, the financial institutions party thereto as lenders, and Navidea Biopharmaceuticals, Inc. as borrower (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 June 28, 2013).
10.53	Series HH Warrant to purchase common stock of Navidea Biopharmaceuticals, Inc. issued to GE Capital Equity Investments, Inc., dated June 25, 2013 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 28, 2013).
10.54	Series HH Warrant to purchase common stock of Navidea Biopharmaceuticals, Inc. issued to MidCap Financial SBIC, LP, dated June 25, 2013 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 28, 2013).

10.55	Subordination Agreement, dated June 25, 2013, among Platinum-Montaur Life Sciences LLC, General Electric Capital Corporation, and Navidea Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed June 28, 2013).
10.56	[^{123}I]NAV5001 Clinical Supply Agreement, dated May 10, 2013, by and between Nordion (Canada) Inc. and Navidea Biopharmaceuticals, Inc. (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 May 16, 2013).
10.57	Underwriting Agreement, dated April 23, 2013, by and between Navidea Biopharmaceuticals, Inc. and Ladenburg Thalmann & Co. Inc. as the sole underwriter (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 24, 2013).
10.58	Loan and Security Agreement, dated March 4, 2014, among Oxford Finance LLC, as collateral agent, the Lenders listed on Schedule 1.1 thereof or otherwise a party thereto from time to time including Oxford in its capacity as a Lender, and Navidea Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 7, 2014).
10.59	Subordination Agreement, dated March 4, 2014, by and among Platinum-Montaur Life Sciences LLC and Oxford Finance LLC, and consented to and acknowledged by Navidea Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed March 7, 2014).
10.6	Form of Series KK Warrants to purchase common stock of Navidea Biopharmaceuticals, Inc. issued to Oxford Finance LLC on March 4, 2014 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed March 7, 2014).
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 *

^ Management contract or compensatory plan or arrangement.

* Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.
Dated: March 14, 2014

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)

By: /s/ Mark J. Pykett
Mark J. Pykett
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 and Chief Executive Officer (principal executive officer)	March 14, 2014
/s/ Brent L. Larson* Brent L. Larson	Executive Vice President and Chief Financial Officer (principal financial officer)	March 14, 2014
/s/ Gordon A. Troup* Gordon A. Troup	Chairman, Director	March 14, 2014
/s/ Peter F. Drake* Peter F. Drake	Director	March 14, 2014
/s/ Brendan A. Ford* Brendan A. Ford	Director	March 14, 2014
/s/ Michael M. Goldberg* Michael M. Goldberg	Director	March 14, 2014
/s/ Perry A. Karsen* Perry A. Karsen	Director	March 14, 2014
/s/ Eric K. Rowinsky* Eric K. Rowinsky	Director	March 14, 2014

*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, 2013 and 2012
and for Each of the
Three Years in the Period Ended
December 31, 2013

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 and Stockholders
Navidea Biopharmaceuticals, Inc.
Dublin, Ohio

We have audited the accompanying consolidated balance sheets of Navidea Biopharmaceuticals, Inc. as of December 31, 2013 and 2012 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, 2013. 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, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, 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, 2013, based on criteria established in Internal Control–Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 14, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Chicago, Illinois
March 14, 2014

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

ASSETS	December 31, 2013	December 31, 2012
Current assets:		
Cash	$32,939,026	$9,118,564
Accounts receivable	1,150,626	17,605
Inventory	2,232,436	297,500
Prepaid expenses and other	1,009,094	1,183,714
Total current assets	37,331,182	10,617,383
Property and equipment	3,609,059	2,026,895
Less accumulated depreciation and amortization	1,483,676	1,092,317
	2,125,383	934,578
Patents and trademarks	163,302	115,053
Less accumulated amortization	26,448	22,571
	136,854	92,482
Deferred debt issuance costs and other	723,098	327,954
Total assets	$40,316,517	$11,972,397

Continued

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets, continued

LIABILITIES AND STOCKHOLDERS' DEFICIT	December 31, 2013	December 31, 2012
Current liabilities:		
Accounts payable	$2,422,349	$1,417,463
Accrued liabilities and other	4,772,963	2,016,358
Notes payable, current, net of discounts of $743,062 and $202,287, respectively	4,095,650	2,756,718
Total current liabilities	11,290,962	6,190,539
Notes payable, net of discounts of $856,746 and $93,038, respectively	23,572,603	6,930,112
Derivative liabilities	7,692,087	—
Other liabilities	1,770,452	257,122
Total liabilities	44,326,104	13,377,773
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 7,565 and 6,938 Series B shares issued and outstanding at December 31, 2013 and 2012, respectively	8	7
Common stock; $.001 par value; 200,000,000 shares authorized; 135,919,423 and 113,018,772 shares issued and outstanding at December 31, 2013 and 2012, respectively	135,919	113,019
Additional paid-in capital	313,111,788	273,039,442
Accumulated deficit	(317,257,302)	(274,557,844)
Total stockholders' deficit	(4,009,587)	(1,405,376)
Total liabilities and stockholders' deficit	$40,316,517	$11,972,397

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Operations

	Years Ended December 31,		
	2013	2012	2011
Revenue:			
Net sales	$614,423	$—	$—
Grant and other revenue	516,207	78,738	597,729
Total revenue	1,130,630	78,738	597,729
Cost of goods sold	332,815	—	—
Gross profit	797,815	78,738	597,729
Operating expenses:			
Research and development	23,710,183	16,890,482	15,154,365
Selling, general and administrative	15,525,946	11,177,559	9,547,779
Total operating expenses	39,236,129	28,068,041	24,702,144
Loss from operations	(38,438,314)	(27,989,303)	(24,104,415)
Other income (expense):			
Interest income	18,838	25,044	25,755
Interest expense	(2,778,780)	(1,166,332)	(13,330)
Change in fair value of financial instruments	(112,073)	32,110	(952,375)
Loss on extinguishment of debt	(1,372,266)	—	—
Other, net	(16,863)	(58,723)	(3,211)
Total other expense, net	(4,261,144)	(1,167,901)	(943,161)
Loss before income taxes	(42,699,458)	(29,157,204)	(25,047,576)
Benefit from income taxes	—	—	7,880,143
Loss from continuing operations	(42,699,458)	(29,157,204)	(17,167,433)
Discontinued operations, net of tax effect:			
Gain on sale – GDS Business	—	—	19,450,891
Income from operations	—	—	3,329,534
Net (loss) income	(42,699,458)	(29,157,204)	5,612,992
Preferred stock dividends	—	(43,333)	(100,000)
Net (loss) income attributable to common stockholders	$(42,699,458)	$(29,200,537)	$5,512,992
(Loss) income per common share (basic and diluted):			
Continuing operations	$(0.35)	$(0.29)	$(0.17)
Discontinued operations	$—	$—	$0.23
Attributable to common stockholders	$(0.35)	$(0.29)	$0.06

Weighted average shares outstanding:			
Basic and diluted	121,808,986	99,059,997	90,509,326

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 Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
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, net	—	—	6,020,000	6,020	1,972,581	—	1,978,601
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)
Issued stock in connection with public offerings, net of costs	—	—	14,205,770	14,205	38,117,267	—	38,131,472
Issued stock upon exercise of stock options, net	—	—	39,649	40	(9,201)	—	(9,161)
Issued restricted stock	—	—	73,500	74	—	—	74
Canceled stock to pay employee tax obligations	—	—	(194,077)	(194)	(610,362)	—	(610,556)
Canceled forfeited restricted stock	—	—	(29,250)	(29)	—	—	(29)
Issued stock upon exercise of warrants	2,365	2	3,000,000	3,000	6,158,330	—	6,161,332
Issued stock to 401(k) plan	—	—	22,126	22	66,755	—	66,777
Issued stock for payment of milestone fee	—	—	100,000	100	165,900	—	166,000
Conversion of Series B preferred stock to common stock	(1,738)	(1)	5,682,933	5,682	(5,681)	—	—
Issued warrants in connection with debt issuance	—	—	—	—	967,115	—	967,115
Issued warrants in connection with public offering	—	—	—	—	(7,686,046)	—	(7,686,046)
Stock compensation expense	—	—	—	—	2,908,269	—	2,908,269
Net loss	—	—	—	—	—	(42,699,458)	(42,699,458)
Balance, December 31, 2013	7,565	$8	135,919,423	$135,919	$313,111,788	$(317,257,302)	$(4,009,587)

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2013	2012	2011
Cash flows from operating activities:			
Net (loss) income	$(42,699,458)	$(29,157,204)	$5,612,992
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Depreciation and amortization of property and equipment	400,304	198,822	175,296
Amortization of intangible assets	3,877	1,400	1,248
Loss on disposal and abandonment of assets	1,160	2,534	18,645
Amortization of debt discount and debt offering costs	765,263	544,517	3,805
Stock compensation expense	2,908,269	2,304,118	3,592,090
Change in fair value of financial instruments	112,073	(32,110)	952,375
Loss on extinguishment of debt	1,372,266	—	—
Gain on sale of GDS Business, before income tax	—	—	(26,173,805)
Issuance of common stock for payment of milestone and sublicense fees	166,000	1,146,000	—
Other	71,209	61,928	61,971
Change in operating assets and liabilities:			
Accounts receivable	(1,042,280)	6,499	(219,021)
Inventory	(1,934,936)	524,049	(53,289)
Prepaid expenses and other assets	84,493	(385,125)	(40,204)
Accounts payable	1,003,515	736,109	(538,666)
Accrued liabilities and other liabilities	3,176,170	125,144	487,055
Deferred revenue	—	—	109,503
Net cash used in operating activities	(35,612,075)	(23,923,319)	(16,010,005)
Cash flows from investing activities:			
Purchases of equipment	(1,239,666)	(663,348)	(183,830)
Proceeds from sales of equipment	—	—	1,000
Proceeds from sale of GDS Business, net	—	—	30,159,527
Payments of costs to sell GDS Business	—	—	(2,765,932)
Patent and trademark costs	(52,701)	(8,460)	(52,504)
Net cash (used in) provided by investing activities	(1,292,367)	(671,808)	27,158,261
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	41,303,750	2,724,189	7,198,373
Payment of common stock issuance costs	(1,752,932)	—	—
Payment for common stock repurchased from executives	—	(100,875)	—
Payment of tax withholdings related to stock-based compensation	(659,018)	(8,765)	(2,762,710)
Payment of preferred stock dividends	—	(100,000)	(100,000)
Proceeds from notes payable	29,000,000	4,000,000	7,000,000
Payment of debt issuance costs	(1,177,293)	(153,949)	(189,390)
Principal payments on notes payable	(5,982,155)	(1,285,046)	(62,411)
Payments under capital leases	(7,448)	(5,867)	(8,620)
Net cash provided by financing activities	60,724,904	5,069,687	11,075,242
Net increase (decrease) increase in cash	23,820,462	(19,525,440)	22,223,498
Cash, beginning of year	9,118,564	28,644,004	6,420,506

Cash, end of year	$32,939,026	$9,118,564	$28,644,004

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. Toward that end, we are currently developing five pharmaceutical platforms:

- Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help evaluate patients with 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. It was approved by the U.S. Food and Drug Administration (FDA) in March 2013, and launched commercially in the United States in May 2013.
- Navidea's Manocept™ platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. This flexible and versatile platform acts as an engine for the design of purpose-built molecules offering the potential to be utilized across a range of diagnostic modalities, including single photon emission computed tomography (SPECT), positron emission tomography (PET), intra-operative and/or optical-fluorescence detection in a variety of disease states.
- NAV4694 is a Fluorine-18 (F-18) radiolabeled 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 (I-123) radiolabeled SPECT imaging agent being developed as an aid in the diagnosis of Parkinson's disease (PD) and other movement disorders, with potential use as a diagnostic aid in dementia.
- NAV1800 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.

The last four of these drug product platforms 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 for the year ended December 31, 2011.

In December 2001, we acquired Cardiosonix Ltd. (Cardiosonix), an Israeli company with a blood flow measurement device product line in the early stages of commercialization. In August 2009, the Company's Board of Directors decided to discontinue the operations and attempt to sell Cardiosonix. However, we were obligated to continue to service and support the Cardiosonix devices through 2013. The Company has not received significant expressions of interest in the Cardiosonix business and as such, we continue to wind down our activities in this area until a final shutdown of operations or a sale of the business unit is completed.

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. Navidea owned 90% of the outstanding shares of Cira Bio with the remaining shares being held by the principals of Cira LLC. In October 2013, Cira Bio was dissolved in its entirety.

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 and our wholly-owned subsidiary, Cardiosonix. Our consolidated financial statements also include the accounts of our former wholly-owned subsidiary, Cira Bio, through the date of dissolution in October 2013. All significant inter-company accounts were eliminated in consolidation.

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

d. Financial Instruments and Fair Value: 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, 2013 and 2012 primarily consists of the face amount of the notes less unamortized discounts. See Note 9. At December 31, 2013, certain notes payable were also required to be recorded at fair value. The estimated fair value of our debt was calculated using a discounted cash flow analysis as well as a Monte Carlo simulation in 2013. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. Unrealized gains and losses on the fair value of the debt are classified in other expenses as a change in the fair value of financial instruments in the statements of operations. At December 31, 2013, the fair value of our notes payable is approximately $29.9 million, which approximates face value.

(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, 2013 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 the fair value of financial instruments in the statements of operations. See Note 11.

e. Stock-Based Compensation: At December 31, 2013, 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.

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, 2013, 2012 and 2011 are noted in the following table:

	2013	2012	2011
Expected volatility	60%-71%	63%-72%	64%-71%
Weighted-average volatility	65%	65%	69%
Expected dividends	—	—	—
Expected term (in years)	5.0-6.2	5.0-6.3	5.3-6.3
Risk-free rate	1.0%-1.9%	0.6%-1.2%	1.3%-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. 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 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.

g. Accounts Receivable: Accounts receivable are recorded net of an allowance for doubtful accounts. We estimate an allowance for doubtful accounts based on a review and assessment of specific accounts receivable and write off accounts when deemed uncollectible. At December 31, 2013, approximately 69% and 22% of accounts receivable were due from the landlord of our Dublin office space for tenant improvements and from Cardinal Health, respectively, and there was no allowance for doubtful accounts. We do not believe we are exposed to significant credit risk related to either the landlord or Cardinal Health based on the overall financial strength and credit worthiness of the entities. We believe that we have adequately addressed other credit risks in estimating the allowance for doubtful accounts.

h. 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. 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, estimated future sales and production rates, and estimated shelf lives. See Note 6.

i. 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. Depreciation and amortization related to equipment under capital leases and leasehold improvements is recognized 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.

j. 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.

k. 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.

l. Deferred Debt Issuance Costs: We defer costs associated with the issuance of notes payable and amortize those costs over the term of the notes using the effective interest method. During the years ended December 31, 2013 and 2011, we incurred $881,000 and $593,000, respectively, of debt issuance costs related to notes payable. During 2013, 2012 and 2011, we recorded amortization of $309,000, $296,000, and $2,000, respectively, of deferred debt issuance costs. Deferred debt issuance costs and other assets at December 31, 2013 and 2012 includes net deferred debt issuance costs of $691,000 and $295,000, respectively. See Note 9.

m. Leases: Leases are categorized as either operating or capital leases at inception. Operating lease costs are recognized on a straight-line basis over the term of the lease. An asset and a corresponding liability for the capital lease obligation are established for the cost of capital leases. The capital lease obligation is amortized over the life of the lease. For build-to-suit leases, the Company establishes an asset and liability for the estimated construction costs incurred to the extent that it is involved in the construction of structural improvements or takes construction risk prior to the commencement of the lease. Upon occupancy of facilities under build-to-suit leases, the Company assesses whether these arrangements qualify for sales recognition under the sale-leaseback accounting guidance. If a lease does not meet the criteria to qualify for a sale-leaseback transaction, the established asset and liability remain on the Company's balance sheet. See Note 15.

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

o. Revenue Recognition: We currently generate revenue primarily from sales of Lymphoseek. Our standard shipping terms are FOB shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment from Cardinal Health’s national distribution center to another point of destination. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business.

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

We generate additional revenue from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due. We also recognize revenue from the reimbursement by our partners of certain expenditures for which the Company has principal responsibility.

p. Research and Development Costs: 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, manufacturing-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.

q. 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, 2013 and 2012.

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. See Note 13.

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, 2013 or 2012 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, 2013, tax years 2010-2013 remained subject to examination by federal and state tax authorities.

r. Recent Accounting Developments: In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-2, Comprehensive Income (Topic 220). ASU 2013-2 provides entities with two basic options for reporting the effect of significant reclassifications – either (1) on the face of the statement where net income is presented or (2) as a separate footnote disclosure. Public entities will report reclassifications in both annual and interim periods. Under option 1, the effect of significant reclassifications is presented parenthetically by component of other comprehensive income (OCI) on the respective line items of net income. Entities must also parenthetically report the aggregate tax effect of reclassifications in the income tax expense (benefit) line item. Under option 2, the significant amounts of each component of OCI must be presented in a single footnote. ASU 2013-2 is effective prospectively for reporting periods beginning after December 15, 2012. ASU 2013-2 did not have an effect on our consolidated financial statements.

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (ASU 2013-11). ASU 2013-11 requires an entity to present an unrecognized tax benefit in the financial statements as a reduction to a deferred tax asset for a net operating loss (NOL) carryforward, a similar tax loss, or a tax credit carryforward except when: (1) a NOL carryforward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date under the governing tax law to settle taxes that would result from the disallowance of the tax position; or (2) the entity does not intend to use the deferred tax asset for this purpose (provided that the tax law permits a choice). If either of these conditions exists, an entity should present an unrecognized tax benefit in the financial statements as a liability and should not net the unrecognized tax benefit with a deferred tax asset. ASU 2013-11 does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. ASU 2013-11 should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. We do not expect ASU 2013-11 to have an impact on our consolidated financial statements.

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.

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, net of taxes, have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

	Year Ended December 31, 2011
Net sales	$7,684,689
Cost of goods sold	2,324,427
Gross profit	5,360,262
Operating expenses:	
Research and development	564,194
Selling, general and administrative	308,220
Total operating expenses	872,414
Other expense, net	(1,084)
Income taxes	(1,157,230)
Income from discontinued operations	$3,329,534

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

Beginning in the second quarter of 2013, Platinum-Montaur Life Sciences, LLC (Platinum) has the right to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draws under the Platinum credit facility, under certain circumstances. Platinum's option to convert future draws into common stock was determined to meet the definition of a liability and is included as part of the value of the related notes payable on the consolidated balance sheet. The estimated fair value of the Platinum notes payable is $4.3 million at December 31, 2013, and will continue to be measured on a recurring basis. See Note 10.

In September 2013, in connection with a Securities Purchase Agreement with Crede CG III, Ltd. (Crede), we issued warrants containing certain features that, although they do not require the warrants to be settled in cash, do require the warrants to be classified as liabilities under applicable accounting rules. As a result, the Company recorded derivative liabilities with an estimated fair value of $7.7 million on the date the warrants were issued. The estimated fair value of the liability was $7.7 million as of December 31, 2013, and will continue to be measured on a recurring basis. See Note 11 and 12.

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

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2013

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (a)(b) (Level 3)	Balance as of December 31, 2013
Platinum notes payable	$—	$—	$4,268,062	$4,268,062
Derivative liabilities related to warrants	$—	$7,692,087	$—	$7,692,087

There were no financial assets or liabilities measured at fair value on a recurring basis as of December 31, 2012.

a. Valuation Processes-Level 3 Measurements: Depending on the instrument, the Company utilizes discounted cash flows, option pricing models, or third-party valuation services to estimate the value of their financial assets and liabilities. Valuations using discounted cash flow methods and certain option pricing models such as Black-Scholes are generally conducted by the Company. Valuations using complex models such as Monte Carlo simulation are generally provided to the Company by third-party valuation experts. Each reporting period, the Company provides significant unobservable inputs to the third-party valuation experts based on current internal estimates and forecasts.

b. Sensitivity Analysis-Level 3 Measurements: Changes in the Company's current internal estimates and forecasts are likely to cause material changes in the fair value of the liabilities. The significant unobservable inputs used in the fair value measurement of the liabilities are the amount and timing of future draws expected to be taken under the Platinum Loan Agreement based on current internal forecasts, management's estimate of the likelihood of actually making those draws as opposed to obtaining other sources of financing, and management's estimate of the likelihood of those draws ultimately resulting in Platinum exercising their conversion option under the Platinum Loan Agreement. Significant increases (decreases) in any of the significant unobservable inputs would result in a higher (lower) fair value measurement. A change in one of the inputs would not necessarily result in a directionally similar change in the others.

There were no Level 1 liabilities outstanding at any time during the years ended December 31, 2013 and 2012. A total of $484,419 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 year ended December 31, 2012. There were no transfers in or out of our Level 2 liabilities during the year ended December 31, 2013.

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

4. Stock-Based Compensation

For the years ended December 31, 2013, 2012 and 2011, our total stock-based compensation expense was approximately $2.9 million, $2.3 million and $3.6 million, respectively. We have not recorded any income tax benefit related to stock-based compensation for the years ended December 31, 2013, 2012 and 2011.

A summary of the status of our stock options as of December 31, 2013, and changes during the year then ended, is presented below:

	Year Ended December 31, 2013			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of year	3,412,777	$2.01		
Granted	1,705,725	3.04		
Exercised	(60,000)	0.84		
Cancelled and forfeited	(111,900)	2.98		
Expired	(80,000)	0.31		
Outstanding at end of year	4,866,602	$2.38	7.1 years	$1,870,550
Exercisable at end of year	2,265,581	$1.57	5.2 years	$1,858,263

Following a review undertaken by the Company's Board of Directors and senior management in June 2013, the Company determined that the Board had inadvertently granted stock awards in February 2012 to the Company's Chief Executive Officer, Mark J. Pykett, in excess of the amount then authorized under the 2002 Plan. Consequently, the Board canceled options to purchase 50,000 shares of the Company's common stock issued to Dr. Pykett (the amount by which the grants to Dr. Pykett in February 2012 exceeded the 2002 Plan's share limitation), and Dr. Pykett agreed to the cancellation.

The weighted average grant-date fair value of options granted in 2013, 2012, and 2011 was $1.81, $1.86 and $2.22, respectively. During 2013, 60,000 stock options with an aggregate intrinsic value of $126,000 were exercised in exchange for issuance of 39,649 shares of our common stock, resulting in gross proceeds of $39,000. During 2012, 1,232,001 stock options with an aggregate intrinsic value of $3.4 million were exercised in exchange for issuance of 1,225,271 shares of our common stock, resulting in gross proceeds of $752,000. During 2011, 2,697,833 stock options with an aggregate intrinsic value of $9.6 million were exercised in exchange for issuance of 1,832,673 shares of our common stock, resulting in gross proceeds of $225,000. During 2013, 2012 and 2011, we paid tax withholdings related to stock options exercised of $659,000, $9,000, and $2.8 million, respectively. In 2013, 2012, and 2011, the aggregate fair value of stock options vested during the year was $36,000, $460,000 and $998,000, respectively.

A summary of the status of our unvested restricted stock as of December 31, 2013, and changes during the year then ended, is presented below:

	Year Ended December 31, 2013	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of year	1,335,000	$2.28
Granted	73,500	2.67
Vested	(745,000)	1.86
Forfeited	(29,250)	4.23
Expired	—	—
Unvested at end of year	634,250	$2.73

In February 2013, 100,000 shares of restricted stock with an aggregate fair value of $308,000 vested as scheduled according to the terms of a restricted stock agreement. In March 2013, the Company received FDA approval to market Lymphoseek®. As a result of the Lymphoseek approval, 560,000 shares of restricted stock vested with an aggregate fair value of $1.8 million.

In April 2013, 85,000 shares of restricted stock held by non-employee directors with an aggregate fair value of $224,000 vested as scheduled according to the terms of the restricted stock agreements. In July 2013, 29,250 shares of restricted stock with an aggregate fair value of $83,000 were forfeited as a result of a non-employee director departing from the Board.

During 2013, 2012 and 2011, 745,000, 30,000 and 1,050,000 shares, respectively, of restricted stock vested with aggregate vest date fair values of $2.3 million, $85,000 and $4.2 million, respectively.

As of December 31, 2013, 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 1.96 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, 2013, 2012 and 2011:

	Years Ended December 31,		
	2013	2012	2011
Net (loss) income	$(42,699,458)	$(29,157,204)	$5,612,992
Preferred stock dividends	—	(43,333)	(100,000)
Net (loss) income attributable to common stockholders	$(42,699,458)	$(29,200,537)	$5,512,992
Weighted average shares outstanding (basic and diluted)	121,808,986	99,059,997	90,509,326
(Loss) income per common share (basic and diluted)	$(0.35)	$(0.29)	$0.06

Earnings (loss) per common share for the years ended December 31, 2013, 2012 and 2011 excludes the effects of 32.2 million, 38.4 million and 55.7 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, 634,250, 1,335,000 and 1,556,000 shares of unvested restricted stock were excluded in determining basic and diluted loss per share for the years ended December 31, 2013, 2012 and 2011, respectively, because such inclusion would be anti-dilutive.

6. Inventory

The components of net inventory at December 31, 2013 and 2012, net of reserves of $0 and $308,000, respectively, are as follows:

	2013	2012
Materials	$652,818	$297,500
Work in process	1,073,568	—

Finished goods	506,050	—
	$2,232,436	$297,500

During 2013 and 2012, we capitalized $2.4 million and $525,000, respectively, of inventory costs associated with our Lymphoseek product. During 2013 and 2012, we wrote off $298,000 and $741,000, respectively, 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.

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	2013	2012
Production machinery and equipment	5 years	$1,239,834	$397,643
Other machinery and equipment, primarily computers and research equipment	3 – 5 years	658,860	581,409
Furniture and fixtures	7 years	439,715	439,716
Software	3 years	544,254	471,811
Leasehold improvements*	Term of Lease	726,396	136,316
		$3,609,059	$2,026,895

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

Property and equipment includes $9,000 and $30,000 of equipment under capital leases with accumulated amortization of $3,000 and $16,000 at December 31, 2013 and 2012, respectively. During 2013, 2012 and 2011, we recorded $400,000, $199,000 and $117,000, respectively, of depreciation and amortization related to property and equipment.

8. Accrued Liabilities and Other

Accrued liabilities and other at December 31, 2013 and 2012 consist of the following:

	2013	2012
Contracted services	$3,325,391	$1,183,805
Compensation	1,124,976	762,266
Accrued Interest	204,792	50,002
Other	117,804	20,285
	$4,772,963	$2,016,358

9. Notes Payable

In December 2011, we executed a Loan and Security Agreement (the Hercules 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 million (the Hercules Note), 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% and (2) Series GG warrants 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 warrants). Additionally, the

Hercules

Loan Agreement provided Navidea with the option to draw a second advance in the principal amount of $3 million if certain conditions were met by June 30, 2012. Such conditions were not met and Hercules no longer had an obligation to provide the additional $3 million. The Hercules Loan Agreement provided for an interest-only period beginning on December 29, 2011 and expiring on July 1, 2012. The principal and interest was to be repaid in 30 equal monthly installments, payable on the first of each month following the expiration of the interest-only period.

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 Hercules Note based on the market price of the Company's stock on the date of the Loan Agreement. In addition, the Series GG warrants were 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 warrants. The estimated fair value of the Series GG warrants was recorded as a discount on the Hercules Note. 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 Hercules Note of $545,366 and the debt issuance costs of $593,339 were being amortized as non-cash interest expense using the effective interest method over the term of the Hercules Loan Agreement.

During 2012, we paid $1.3 million of principal payments on the Hercules Note. During the period from January 1, 2013 through June 24, 2013, we paid an additional $1.3 million of principal payments on the Hercules Note. On June 25, 2013, the Company used a portion of the proceeds from the GECC/MidCap Notes (discussed below) to pay the remaining $4.4 million of principal outstanding on the Hercules Note, as well as a $250,000 end-of-term fee and a $66,000 early payment penalty in accordance with the terms of the Hercules Loan Agreement. We recorded a loss on extinguishment of the Hercules Note of $429,000, consisting of the write-off of the remaining unamortized discount of $187,000 and unamortized debt issuance costs of $176,000, as well as the early payment penalty of $66,000. As of December 31, 2013, the Hercules Note was no longer outstanding.

In July 2012, we entered into an agreement with Platinum-Montaur Life Sciences, LLC (Platinum) to provide us with a credit facility of up to $50 million. Under the terms of the agreement, Platinum committed to extend up to $15 million in debt, which was 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%. In March 2013, the Company received FDA approval to market Lymphoseek. The approval of Lymphoseek resulted in an additional $20 million being made available to the Company under the Platinum credit facility. Another $15 million is potentially available on terms to be negotiated. Principal amounts were due the earlier of two years from the date of draw or June 30, 2016. No conversion features or warrants were initially associated with the facility. We drew a total of $4.0 million under the credit facility in each of the years ended December 31, 2013 and 2012.

In June 2013, we executed a Loan and Security Agreement (the GECC/MidCap Loan Agreement) with General Electric Capital Corporation (GECC) and MidCap Financial SBIC, LP (MidCap), providing for a loan to the Company of $25 million. Pursuant to the GECC/MidCap Loan Agreement, we issued GECC and MidCap: (1) Term Notes in the aggregate principal amount of $25 million, bearing interest at 9.83%, (the GECC/MidCap Notes), and (2) Series HH warrants to purchase an aggregate of 301,205 shares of our common stock at an exercise price of $2.49 per share, expiring in June 2023 (the Series HH Warrants). The GECC/MidCap Loan Agreement provides for an interest-only period beginning on June 25, 2013 and expiring on June 30, 2014. 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, and one final payment in an amount equal to the entire remaining principal balance of the GECC/MidCap Notes on the maturity date. The outstanding balance of the debt is due December 23, 2016. On the date upon which the outstanding principal amount of the loan is paid in full, the Company will be required to pay a non-refundable end-of-term fee equal to 4.0% of the original principal amount of the loan. 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 GECC/MidCap Loan Agreement also specifies certain covenants including the requirement that Navidea maintains a minimum cash balance greater than six times its monthly cash burn amount and provides certain information, such as financial statements and budgets, on a periodic basis. As of December 31, 2013, the minimum cash balance required was $22.6 million, and we were in compliance with all covenants of the Loan Agreement. As of December 31, 2013, the outstanding principal

balance of the GECC/MidCap Loan Agreement was $25.0 million.

The Company recorded a debt discount related to the issuance of the Series HH warrants and other fees to the lenders totaling $1.9 million. Debt issuance costs directly attributable to the GECC/MidCap Loan Agreement, totaling $881,000, were recorded as other assets on the balance sheet on the closing date. The debt discount and debt issuance costs are being amortized as non-cash interest expense using the effective interest method over the term of the GECC/MidCap Loan Agreement. As of December 31, 2013, the balance of the debt discount was $1.6 million and the net balance of the debt issuance costs was $691,000.

In June 2013, concurrent with entering into the GECC/MidCap Loan Agreement, the Company and Platinum entered into an Amendment to the July 2012 credit facility between the Company and Platinum (the Platinum Amendment). Navidea, Platinum, and GECC/MidCap also entered into a Subordination Agreement (the GECC/MidCap Subordination Agreement), providing for subordination of the Company's indebtedness under the Platinum credit facility to the Company's indebtedness under the GECC/MidCap Loan Agreement, among other customary terms and conditions.

In connection with the execution of the Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the Amended Platinum Note) to Platinum, which amends and restates the original promissory note, issued to Platinum, in the principal amount of up to $35.0 million. The Amended Platinum Note also adjusts the interest rate to the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10%; or (c) the highest rate of interest then payable pursuant to the GECC/MidCap Loan Agreement plus 0.125% (effective interest rate at December 31, 2013 was 10%). In addition, the Platinum Amendment grants Platinum the right, at Platinum's option, to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draws (the Conversion Amount), beginning on a date two years from the date the draw was advanced, into the number of shares of Navidea's common stock computed by dividing the Conversion Amount by a conversion price equal to the lesser of (i) 90% of the lowest VWAP for the 10 trading days preceding the date of such conversion request, or (ii) the average VWAP for the 10 trading days preceding the date of such conversion request. The Platinum Amendment also provides a conversion right on the same terms with respect to the amount of any mandatory repayment due following the Company achieving $2.0 million in cumulative revenues from sales or licensing of Lymphoseek. The conversion option applies to the Conversion Amount if the Company is prohibited from making such repayment under the terms of the GECC/MidCap Subordination Agreement.

In accordance with current accounting standards, the Platinum Amendment was treated as an extinguishment of debt. The difference between the fair value of the new debt and the carrying value of the original Platinum loan balance was recorded as loss on extinguishment of $943,000. Platinum's option to convert future draws into common stock was determined to meet the definition of a liability. The fair value of the new debt includes the estimated fair value of the embedded conversion option, which was $943,000 on the date of issuance of the Amended Platinum Note. The net increase in the estimated fair value of the Amended Platinum Note of $106,000 was recorded as a non-cash change in fair value of financial instruments during the year ended December 31, 2013. The estimated fair value of the Amended Platinum Note was $4.3 million as of December 31, 2013.

Also in connection with the Platinum Amendment, the Company and Platinum entered into a Warrant Exercise Agreement (Exercise Agreement), pursuant to which Platinum exercised its Series X Warrant and Series AA Warrant for 2,364.9 shares of the Company's Series B Convertible Preferred Stock (the Series B Preferred Stock), convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share). These warrants were exercised on a cashless basis by canceling a portion of the indebtedness outstanding under the Platinum Loan Agreement equal to $4.8 million, the aggregate exercise price of the warrants. As of December 31, 2013, the remaining outstanding principal balance of the Platinum Loan Agreement was approximately $3.2 million, with $31.8 million still available under the credit facility.

During the years ended December 31, 2013, 2012 and 2011, we recorded interest expense of $2.8 million, $1.2 million and $10,000, respectively, related to our notes payable. Of those amounts, $765,000, $545,000 and $4,000, respectively, was non-cash in nature related to amortization of the debt discounts and deferred financing costs related to our notes payable.

Annual principal maturities of our notes payable are $4.8 million, $9.7 million and $13.7 million, in 2014, 2015 and 2016, respectively.

10. Convertible Securities

In June 2010, we entered into a Securities Exchange Agreement with Platinum which caused certain of Platinum's security holdings to be exchanged for 10,000 shares of Series B Preferred Stock, convertible into 32,700,000 shares of common stock. The Series B Preferred Stock is convertible at the option of Platinum 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), which caused certain of the Bupp Investors' security holdings to be exchanged for 1,000 shares of Series C Convertible Preferred Stock (the Series C Preferred Stock), convertible into 3,226,000 shares of common stock.

In May 2011, Platinum 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, Platinum 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. (PPVAF), an affiliate of Platinum, pursuant to which PPVAF exchanged 3,001,860 shares of our common stock owned by PPVAF for 918 shares of our Series B Preferred Stock.

In December 2012, we entered into a Waiver Agreement (the Waiver) pursuant to which Platinum and PPVAF, 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 was to remain in effect until December 31, 2013, upon which date all outstanding shares of Series B Preferred Stock were to automatically convert into common stock pursuant to the terms of the Certificate. In addition, we amended the terms of Platinum'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.

As discussed in Note 9, in June 2013, the Company and Platinum entered into a Warrant Exercise Agreement, pursuant to which Platinum exercised its Series X warrant and Series AA warrant for 2,364.9 shares of the Company's Series B Preferred Stock, convertible into 7,733,223 shares of our common stock in the aggregate.

Also in June 2013, we amended the Series B Preferred Stock to eliminate the date certain for automatic conversion. As a result of this amendment, all outstanding shares of Series B Preferred Stock will automatically convert into common stock of the Company at the conversion rate of 3,270 shares of common stock for each share of Series B Preferred Stock upon the earlier to occur of either of the following: (i) the closing of a firm commitment underwritten public offering of common stock of the Company pursuant to an effective registration statement under Section 5 of the Securities Act in which the gross cash proceeds to the Company (before underwriting discounts, commissions and fees) from such public offering are at least $10,000,000, or (ii) one hundred eighty (180) days following the first trading date upon which the price per share of the common stock equals or exceeds $7.00 per share, but excluding from such 180-day period any trading day on which the price is less than $5.00 per share.

In July 2013, Platinum converted 580 shares of the Series B Preferred Stock into 1,896,600 shares of our common stock under the terms of the Series B Preferred Stock. In September 2013, Platinum converted 710.9 shares of the Series B Preferred Stock into 2,324,643 shares of our common stock and in December 2013 Platinum converted 447 shares of the Series B Preferred Stock into 1,461,690 shares of our common stock. Both the September 2013 and December 2013 conversions were completed in accordance with the terms of the Series B Preferred Stock.

As of December 31, 2013, there are 7,565 shares of Series B Preferred Stock outstanding which are convertible into 24,737,550 shares of our common stock.

11. Derivative Instruments

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

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.

As discussed in Note 9, 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 9.

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.

In September 2013, we entered into a Securities Purchase Agreement with Crede CG III, Ltd. (Crede) for a registered direct public offering. The Series JJ warrants issued in connection with the Securities Purchase Agreement are not considered to be indexed to the Company's stock due to certain features within the warrant, and as such, the warrants are required to be classified as liabilities. As a result, the Company recorded derivative liabilities with an estimated fair value of $7.7 million on the date the warrants were issued.

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, 2013, 2012 and 2011 resulted in net increases (decreases) in non-cash expense (income) of $6,000, ($32,000) and $952,000. The total estimated fair value of our derivative liabilities was $7.7 million and $569,000 as of December 31, 2013 and 2011, respectively. No derivative liabilities were outstanding as of December 31, 2012.

12. Equity

a. Common Stock Public Offerings: In February 2013, we completed a public offering of 1,542,389 shares of the Company's common stock at a price of $3.10 per share (the February 2013 Offering). The net proceeds to the Company were approximately $4.5 million after deducting expenses associated with the February 2013 Offering. In April 2013, we completed another public offering of 2,100,000 shares of the Company's common stock at a price of $2.43 per share (the April 2013 Offering). The net proceeds to the Company were approximately $4.8 million after deducting expenses associated with the April 2013 Offering. The February 2013 and April 2013 Offerings were underwritten by Ladenburg Thalmann & Co. Inc. and were made pursuant to the Company's existing effective shelf registration statement on Form S-3.

In September 2013, we entered into a Securities Purchase Agreement with Crede for a registered direct public offering of 10,563,381 shares of our common stock at a price of $2.84 per share for total gross proceeds of $30.0 million. In addition to the common stock, we issued Series JJ warrants to purchase 3,169,015 shares of our common stock at an exercise price of $3.83 per share, expiring on September 24, 2016. The net proceeds to the Company were approximately $28.8 million after deducting expenses associated with the Securities Purchase Agreement, including placement agent fees of $999,000 (3.3% of the gross proceeds). The common stock, warrants, and shares of common stock underlying the warrants were issued pursuant to the Company's existing effective shelf registration statement on Form S-3.

b. Stock Warrants: At December 31, 2013, there are 4.5 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from $1.97 to $3.83 per share with a weighted average exercise price per share of $3.39.

The following table summarizes information about our outstanding warrants at December 31, 2013:

	Exercise Price	Number of Warrants	Expiration Date
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
Series HH	2.49	301,205	June 2023
Series II	3.04	275,000	June 2018
Series JJ	3.83	3,169,015	September 2016
	$3.39 [1]	4,542,764	

[1] Weighted average exercise price.

During 2012, Platinum 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, Platinum exercised 3,000,000 of their Series X warrants in exchange for the issuance of 3,000,000 shares of our common stock, resulting in gross proceeds of $1,380,000.

In June 2013, pursuant to the Exercise Agreement, Platinum exercised its Series X warrant and Series AA warrant for 2,364.9 shares of the Company’s Series B which are convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share). The warrants were exercised on a cashless basis by cancelling a portion of the indebtedness outstanding under the Platinum Loan Agreement equal to $4,781,333, the aggregate exercise price of the warrants.

Also in June 2013 and pursuant to the GECC/MidCap Loan Agreement, the Company issued to GECC/MidCap Series HH warrants to purchase an aggregate of 301,205 shares of our common stock at an exercise price of $2.49 per share, expiring in June 2023.

In addition, in June 2013 we issued five-year Series II warrants to purchase 275,000 shares of our common stock at an exercise price of $3.04 per share to an investment advisory firm in connection with the GECC transaction.

In September 2013, in connection with the Crede Securities Purchase Agreement, the Company issued to Crede Series JJ warrants to purchase 3,169,015 shares of our common stock at an exercise price of $3.83 per share, expiring in September 2016. Crede can exercise the Series JJ warrants at any time at a strike price of $3.83. The warrant agreement also provides for the potential exchange of warrants into Navidea common stock for no additional consideration starting six months after the date of the Securities Purchase Agreement if, at the time of the exchange, the closing bid price for Navidea's common stock is below $3.83. The amount of shares issuable on a potential exchange is based on dividing a Black-Scholes valuation of the warrants by the closing bid price for Navidea's common stock on the date of the exchange. However, as a number of the key inputs to the Black-Scholes calculation are fixed under the terms of the warrant agreement, the Company does not expect the Black-Scholes valuation on the date of a potential exchange to vary materially from the derivative liability of $7.7 million which was reported related to the Series JJ warrants as of December 31, 2013. Based on this valuation, the Company has estimated the number of shares issuable on a potential exchange to be between 2.1 million shares (based on an exchange price of $3.83) and 3.8 million shares (based on the floor exchange price of $2.00).

c. Common Stock Reserved: As of December 31, 2013, we have reserved 34,146,916 shares of authorized common stock for the exercise of all outstanding options, warrants, and convertible preferred stock.

13. Income Taxes

As of December 31, 2013 and 2012, our deferred tax assets were approximately $49.2 million and $33.7 million, respectively. The components of our deferred tax assets are summarized as follows:

	As of December 31,	
	2013	2012
Deferred tax assets:		
Net operating loss carryforwards	$37,191,826	$24,767,569
R&D credit carryforwards	7,388,463	6,546,049
Temporary differences	4,624,832	2,408,108
Deferred tax assets before valuation allowance	49,205,121	33,721,726
Valuation allowance	(49,205,121)	(33,721,726)
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, 2013 and 2012.

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, 2013.

As of December 31, 2013 and 2012, we had U.S. net operating loss carryforwards of approximately $118.5 million and $80.9 million, respectively. Of that amount, $15.2 million and $14.1 million relates to stock-based compensation tax deductions in excess of book compensation expense (APIC NOLs) as of December 31, 2013 and 2012, 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, 2013 and 2012, we had U.S. R&D credit carryforwards of approximately $7.4 million and $6.5 million, respectively.

U.S. net operating loss carryforwards of $20.8 million and R&D credit carryforwards of $1.1 million expired during 2012. There were no expirations during 2013. 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, 2013	
Generated	Expiration	U.S. Net Operating Loss Carryforwards	U.S. R&D Credit Carryforwards
1998	2018	$17,142,781	$1,173,387
1999	2019	—	130,359
2000	2020	—	71,713
2001	2021	—	39,128
2002	2022	1,282,447	5,350
2003	2023	337,714	2,905
2004	2024	1,237,146	22,861
2005	2025	3,246,062	218,332
2006	2026	3,127,238	365,541
2007	2027	2,863,443	342,898
2008	2028	2,826,656	531,539
2009	2029	13,753,769	596,843
2010	2030	5,425,105	1,094,449
2011	2031	1,904,744	1,950,744
2012	2032	28,541,353	468,008
2013	2033	36,840,453	374,406
Total carryforwards		$118,528,911	$7,388,463

During the years ended December 31, 2013, 2012, and 2011, Cardiosonix recorded losses for financial reporting purposes of $13,000, $14,000, and $19,000, respectively. As of December 31, 2013 and 2012, 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, 2013 and 2012.

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 2013, a Section 382 study was completed and the Company does not believe that a Section 382 ownership change has occurred 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,								
	2013			2012			2011		
	Amount	%		Amount	%		Amount	%	
Benefit at statutory rate	$(14,517,816)	(34.0	)%	$(9,913,450)	(34.0	)%	$(8,516,176)	(34.0	)%
Adjustments to valuation allowance	15,399,021	36.1	%	8,604,147	29.5	%	—	—	
Adjustments to R&D credit carryforwards	(842,414)	(2.0	)%	1,064,623	3.7	%	—	—	
Permanent items and other	(38,791)	(0.1	)%	244,680	0.8	%	636,033	2.5	%
Benefit per financial statements	$—			$—			$(7,880,143)		

14. Agreements

a. Supply Agreements: In November 2009, we entered into a manufacture and supply agreement with Reliable Biopharmaceutical Corporation (Reliable) for the manufacture and supply of the 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 $666,000, $939,000, and $544,000 for the years ended December 31, 2013, 2012 and 2011. As of December 31, 2013, we have no purchase orders outstanding under the manufacture and supply agreement with Reliable.

In May 2013, we entered into a clinical supply agreement with Nordion (Canada) Inc. (Nordion) for the manufacture and supply of NAV5001 clinical trial material. The initial three year term expires in May 2016. Navidea may terminate this agreement without cause or penalty upon 180 days prior written notice to Nordion. Upon such termination, Nordion will be entitled to retain all amounts paid by Navidea, and Navidea shall pay to Nordion any undisputed, unpaid amounts due or earned by Nordion. Either party may terminate upon material breach by the other party which is not cured within 30 days from the date of written notice of the breach. Total purchases under the manufacturing agreement were $771,000 for the year ended December 31, 2013. As of December 31, 2013, we have issued purchase orders under the agreement with Nordion for $314,000 of our products for delivery through June 2014.

In August 2013, we entered into a manufacturing services agreement with PETNET Solutions, Inc. (PETNET) for the manufacturing and distribution of NAV4694. The initial three-year term of the agreement expires in August 2016. The agreement will automatically renew for additional one-year terms, unless either party gives written notice to the other at least 60 days prior to the end of the initial term. Either party may terminate upon material breach by the other party which is not cured within 30 days from the date of written notice of the breach. Total purchases under the manufacturing agreement were $1.4 million for the year ended December 31, 2013. As of December 31, 2013, we have issued purchase orders under the agreement with PETNET for $1.4 million of our products for delivery through February 2014.

In September 2013, we entered into a manufacturing services agreement with OSO BioPharmaceuticals Manufacturing, LLC (OsoBio) for contract pharmaceutical development, manufacturing, packaging and analytical services for Lymphoseek. The initial term of the agreement expires in December 2016, and automatically renews for additional two-year periods unless written notice is provided at least 12 months prior to the expiration of the initial term. 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. During the term of agreement OsoBio will be the primary supplier of the manufacturing services for Lymphoseek. In consideration for these services, the Company will pay a unit pricing fee. In addition, the Company will also pay OsoBio a fee for regulatory support services. Total purchases under the manufacturing services agreement were $1.2 million for the year ended December 31, 2013. As of December 31, 2013, we have no purchase orders outstanding under the manufacturing services agreement with OsoBio.

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 $273,000, $33,000, and $98,000 in 2013, 2012 and 2011, respectively, and were recorded in cost of goods sold following the U.S. commercial launch of Lymphoseek in 2013, or in research and development expenses prior to the product launch.

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 $29,000, $31,000 and $28,000 in 2013, 2012 and 2011, 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 $5,000, $14,000 and $5.0 million in 2013, 2012 and 2011, respectively, and were recorded in research and development expenses.

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 $366,000 and $1.8 million in 2013 and 2012, respectively, 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 2013, we have paid the OCS a total of $84,000 in royalties related to sales of products developed under this program. As of December 31, 2013, we have no accrued obligations for royalties.

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.

c. Employment Agreements: We maintain employment agreements with six of our senior officers. The employment agreements contain termination and/or change in control provisions that would entitle each of the officers to 1.1 to 2.1 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, 2013, 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.

15. Leases

We lease certain office equipment under a capital lease which expires in 2016. We also lease office space in Ohio under an operating lease that expires in October 2022 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
2014	$3,039	$288,900
2015	3,039	266,456
2016	2,279	272,428
2017	—	278,564
2018	—	284,886
	8,357	$1,391,234
Less amount representing interest	1,427	
Present value of net minimum lease payments	6,930	
Less current portion	2,225	
Capital lease obligations, excluding current portion	$4,705	

Total rental expense was $400,000, $211,000 and $154,000 for the years ended December 31, 2013, 2012 and 2011, respectively.

16. Employee Benefit Plan

We maintain an employee benefit plan under Section 401(k) of the Internal Revenue Code. The plan allows employees to make contributions and we may, but are not obligated to, match a portion of the employee's contribution with our common stock, up to a defined maximum. We also pay certain expenses related to maintaining the plan. We recorded expenses related to our 401(k) plan of $104,000, $71,000, and $56,000 during 2013, 2012 and 2011, respectively.

17. Supplemental Disclosure for Statements of Cash Flows

During 2013, 2012 and 2011, we paid interest aggregating $1.9 million, $647,000, and $4,000, respectively. During 2013, we issued 100,000 shares of our common stock as partial payment of a milestone fee. During 2012, we issued 300,000 shares of our common stock as partial payment for the execution of a sublicense agreement. During 2013, 2012, and 2011, we issued 22,126, 17,390, and 35,233 shares of our common stock, respectively, as matching contributions to our 401(k) Plan. During 2011, we transferred $25,000 of GDS Business inventory to fixed assets related to the creation and maintenance of a pool of service loaner equipment. During 2012, we prepaid $267,000 of insurance premiums through the issuance of a note payable to a finance company with an interest rate of 2.8%. During 2012, we purchased equipment under a capital lease totaling $9,000.

During 2013, the Company and Platinum entered into an Exercise Agreement, pursuant to which Platinum exercised its Series X Warrant and Series AA Warrant for 2,364.9 shares of the Company’s Series B Preferred Stock. These warrants were exercised on a cashless basis by canceling a portion of the indebtedness outstanding under the Platinum Loan Agreement equal to $4.8 million, the aggregate exercise price of the warrants.

During 2013, in conjunction with the GECC/MidCap Loan Agreement and the Crede Securities Purchase Agreement, we issued warrants with estimated fair values of $631,000 and $7.7 million, respectively. Additionally, $1.0 million of the debt discount fees related to the GECC/MidCap Loan Agreement have been deferred through the maturity date of the loan.

18. Contingencies

We are subject to legal proceedings and claims that arise in the ordinary course of business. We are not presently involved in any material litigation. In accordance with ASC Topic 450 - Contingencies, we make a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Although the outcome of any litigation is uncertain, in our opinion, the amount of ultimate liability, if any, with respect to these actions will not materially affect our financial position.

19. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for the fiscal 2013 and 2012 are presented in the following table, in thousands, except per share data:

	For the Quarter Ending			
	March 31	June 30	September 30	December 31
2013:				
Net sales	$—	$128	$144	$343
Grant and other revenue	—	67	257	192
Gross profit	—	90	325	383
Operating expenses	7,004	8,546	10,250	13,436
Operating loss	(7,004)	(8,456)	(9,925)	(13,053)
Net loss	(7,341)	(10,300)	(11,306)	(13,752)
Net loss attributable to common stockholders	(7,341)	(10,300)	(11,306)	(13,752)
Basic and diluted net loss per share (1)	$(0.06)	$(0.09)	$(0.09)	$(0.10)
2012:				
Net sales	$—	$—	$—	$—
Grant and other revenue	12	60	—	7
Gross profit	12	60	—	7
Operating expenses	6,518	5,447	9,069	7,033
Operating loss	(6,506)	(5,387)	(9,069)	(7,026)
Net loss	(6,989)	(5,835)	(9,099)	(7,235)
Net loss attributable to common stockholders	(7,014)	(5,860)	(9,124)	(7,203)
Basic and diluted net loss per share (1)	$(0.07)	$(0.06)	$(0.09)	$(0.07)

(1) Net loss per share is computed independently for each of the quarters presented. Therefore the sum of the quarterly per-share calculations will not necessarily equal the annual per share calculation.

20. Subsequent Events

a. Notes Payable: In March 2014, we executed a Loan and Security Agreement the (Oxford Loan Agreement) with Oxford Finance, LLC (Oxford), providing for a loan to the Company of $30 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) a Term Loan in the aggregate principal amount of $30,000,000, bearing interest at 8.5%. (the Oxford Term Loan), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of common stock at an exercise price of $1.918 per share, expiring in March 2021 (the Series KK warrants). The Oxford Loan Agreement provides for a one year interest-only period beginning in March 2014, extendable to three years on achievement of certain milestones and certain end-of-term fees. The principal and interest are to be repaid in 24 to 48 equal monthly installments, depending on achievement of certain milestones. The outstanding balance of the debt is due March 1, 2019. The Oxford Term Loan 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 Oxford Loan Agreement also specifies certain covenants including the requirement that Navidea provide certain information, such as financial statements and budgets, on a periodic basis. Concurrent with entering the Oxford Loan Agreement, the Company used a portion of the proceeds from the Oxford Loan Agreement to pay the $25.0 million of principal outstanding on the GECC/MidCap Notes, as well as a $1.0 million end-of-term fee and a $500,000 early payment penalty in accordance with the terms of the GECC/MidCap Loan Agreement.

b. Preferred Stock Conversions: Between January 1, 2014, and the filing date of this document, Platinum converted 4,162 shares of the Series B Preferred Stock into 13,609,740 shares of our common stock under the terms of the

Series B Preferred Stock.

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