

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

The aggregate market value of shares of common stock held by non-affiliates of the registrant on June 30, 2016 was \$84,031,238.

The number of shares of common stock outstanding on March 1, 2017 was 161,898,338.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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 market acceptance, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on earnouts, royalties and grant revenue, limited product line and distribution channels, competition, 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. (“Navidea,” the “Company,” or “we”), a Delaware corporation (NYSE MKT: NAVB), is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on our Manocept™ platform to enhance patient care by identifying the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and targeted treatment.

Navidea’s Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Lymphoseek® (technetium Tc 99m tilmanocept) injection, the first product developed and commercialized by Navidea based on the platform.

On March 3, 2017, pursuant to an Asset Purchase Agreement dated November 23, 2016, (the “Purchase Agreement”), the Company completed its previously announced sale to Cardinal Health 414, LLC (“Cardinal Health 414”) of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer (the “Business”), including the Company’s radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration (“FDA”) and similar indications approved by the FDA in the future (the “Product”), in Canada, Mexico and the United States (the “Territory”) (giving effect to the License-Back described below and excluding certain assets specifically retained by the Company) (the “Asset Sale”). Such assets sold in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all right, title and interest in and to the Product, as specified in the Purchase Agreement (the “Acquired Assets”).

In connection with the closing of the Asset Sale, the Company entered into a License-Back Agreement (the “License-Back”) with Cardinal Health 414. Pursuant to the License-Back, Cardinal Health 414 granted to the Company a sublicensable (subject to conditions) and royalty-free license to use certain intellectual property rights included in the Acquired Assets and owned by Cardinal Health 414 as of the closing of the Asset Sale to the extent necessary for the Company to (i) on an exclusive basis, subject to certain conditions, develop, manufacture, market, sell and distribute new pharmaceutical and other products that are not Competing Products (as defined in the License-Back), and (ii) on a non-exclusive basis, develop, manufacture, market, sell and distribute the Product throughout the world other than in the Territory. Subject to the Company’s compliance with certain restrictions in the License-Back, the License-Back also restricts Cardinal Health 414 from using the intellectual property rights included in the Acquired Assets to develop, manufacture, market, sell, or distribute any product other than the Product or other product that (a) accumulates in lymphatic tissue or tumor-draining lymph nodes for the purpose of (1) lymphatic mapping or (2) identifying the existence, location or staging of cancer in a body, or (b) provides for or facilitates any test or procedure that is reasonably substitutable for any test or procedure provided for or facilitated by the Product. Pursuant to the License-Back and subject to rights under existing agreements, Cardinal Health 414 was given a right of first offer to market, sell and/or market any new products developed from the intellectual property rights licensed by Cardinal Health 414 to the Company by the License-Back.

As part of the Asset Sale, the Company and Cardinal Health 414 also entered into ancillary agreements providing for transitional services and other arrangements. The Company amended and restated its license agreement with The Regents of the University of California, San Diego (“UCSD”) pursuant to which UCSD granted a license to the Company to exploit certain intellectual property rights owned by UCSD and, separately, Cardinal Health 414 entered into a license agreement with UCSD pursuant to which UCSD granted a license to Cardinal Health 414 to exploit certain intellectual property rights owned by UCSD for Cardinal Health 414 to sell the Product in the Territory.

In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately \$80.6 million after adjustments based on inventory being transferred and an advance of \$3 million of guaranteed earnout payments as part of the CRG settlement (described below in Item 3 – Legal Proceedings), (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414’s right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG (described below in Item 3 – Legal Proceedings).

Upon closing of the Asset Sale, the Supply and Distribution Agreement, dated November 15, 2007 (as amended, the “Supply and Distribution Agreement”), between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect (other than any indemnification, payment, notification or data sharing obligations which survive the termination). At the closing of the Asset Sale, Cardinal Health 414 paid to the Company \$1.2 million, as an estimate of the accrued revenue sharing payments owed to the Company as of the closing date, net of prior payments.

The Asset Sale to Cardinal Health 414 in March 2017 significantly improved our financial condition and our ability to continue as a going concern. The Company also continues working to establish new sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be supported by our revenues.

Other than Tc 99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, none of the Company’s drug product candidates have been approved for sale in any market.

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 medicines company focused on “NAVigating IDEAs” that result in the development and commercialization of precision diagnostic and therapeutic 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 also 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”). We sold the GDS Business to Devicor Medical Products, Inc. (“Devicor”) in August 2011. 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 through 2017. Based on the 2015 GDS Business revenue, we earned royalty payments of \$1.2 million. We did not earn any such royalty payments prior to 2015 or in 2016.

Following the sale of the GDS business and the subsequent strategic repositioning as a precision medicines company, the Company in-licensed the two neuro-tracer product candidates, NAV4694 and NAV5001. The Company progressed the development of both product candidates over the course of 2012 through 2014, moving both into Phase 3 clinical trials. However, in May 2014, the Navidea Board announced that, based on its belief that the public markets were not giving appropriate value to its Phase 3 pipeline products and were likely penalizing the Company for allocating resources to these programs, the Company would be restructuring its development efforts to focus on cost effective development of the Manocept platform while it sought development partners for NAV4694 and NAV5001. In April 2015, the Company entered into an agreement with Alseres Pharmaceuticals, Inc. (Alseres) to terminate the NAV5001 sub-license agreement. The Company is currently engaged in discussions related to the potential partnering or divestiture of NAV4694.

In December 2014, we announced the formation of a new business unit, Macrophage Therapeutics, to further explore therapeutic applications for the Manocept platform, which was incorporated as Macrophage Therapeutics, Inc. (“MT”) in January 2015. MT has developed preliminary processes for producing the first several therapeutic Manocept immunoconstructs in the MT-1000 drug line, designed to specifically target and kill activated CD206+ macrophages, and the MT-2000 line, which are designed to inhibit the inflammatory activity of activated CD206+ macrophages. The first of these constructs are MT-1001 and MT-2001, both developed from the Manocept platform technology and the efforts of Navidea’s development team and contain a similar chemical scaffold and targeting moieties designed to selectively target CD206+ macrophages. A payload of a select therapeutic molecule is conjugated to each immunoconstruct through a linkage that will release the molecule within the targeted tissue: MT-1001 contains doxorubicin moieties (an anthracycline antitumor antibiotic) conjugated to the Manocept backbone and MT-2001 contains a potent anti-inflammatory agent. MT has contracted with independent facilities to produce sufficient quantities of the MT-1000 and MT-2000 class agents along with the concomitant analytical standards, to provide material for planned preclinical animal studies and future clinical trials.

Our Technology and Product Candidates

Our primary development efforts over the last few years have been focused on diagnostic products, including Lymphoseek which was sold to Cardinal Health 414 in March 2017, as well as other diagnostic and therapeutic line extensions based on our Manocept platform.

Building on the success of Tc 99m tilmanocept, the flexible and versatile Manocept 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.

We have advanced three additional imaging product candidates into clinical testing.

Cardiovascular Disease (“CV”) – We have completed a nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc 99m tilmanocept product dosed subcutaneously. The results of this study were recently published in the *Journal of Infectious Diseases*, confirming that the Tc 99m tilmanocept product can both quantitatively as well as qualitatively target non-calcified plaque in the aortic arch (NIH/NHLBI Grant 1 R43 HL127846-01). We have applied for follow-on NIH/NHLBI support to fund additional clinical studies. These studies are currently under development and design for both Phase 1 and Phase 2 trials.

Rheumatoid Arthritis (“RA”) – We have initiated two dosing studies in RA. The first study, now complete, included 18 subjects (12 with active disease and 6 controls) who were dosed subcutaneously. In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have initiated and partially completed a study dosing the Tc 99m tilmanocept product intravenously (“IV”). These studies have been supported through a Small Business Innovation Research (“SBIR”) grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1).

Kaposi’s Sarcoma (“KS”) – Although we initiated and completed a study of KS in 2015, we received additional funding from the National Institutes of Health (“NIH”) in 2016 to continue studies in this disease. The new support not only continues the imaging of cutaneous elements of this disease but expands this to imaging of visceral disease via IV administration of Tc99m tilmanocept (NIH/NCI 1 R44 CA192859-01A1). Additionally, we received funding to support the therapeutic initiative for KS employing a select form of the class 1000 agent under current evaluation. The Company has already completed a portion of the Phase 1 SBIR portion of this award (1 R44 CA206788-01).

Based on performance in these very large imaging market opportunities the Company anticipates continued investment in these programs including initiating studies designed to obtain new approvals for the Tc 99m tilmanocept product.

Preclinical data generated by the Company in studies using tilmanocept linked to a therapeutic agent also suggest that tilmanocept’s binding affinity to CD206 receptors demonstrates the potential for this technology to be useful in treating diseases linked to the over-activation of macrophages. This includes various cancers as well as autoimmune, infectious, CV, and central nervous system (“CNS”) diseases. Our efforts in this area were further supported by the 2015 formation of MT, a majority-owned subsidiary that was formed specifically to explore therapeutic applications for the Manocept platform.

MT has been set up to pursue the drug delivery model. This model enables the Company to leverage its technology over many potential therapeutic applications and with multiple partners simultaneously without significant capital outlays. To date, the Company has developed two lead families of therapeutic products. The MT1000 class is designed to deplete activated macrophages via apoptosis. The MT2000 class is designed to modulate activated macrophages from a classically activated phenotype to the alternatively activated phenotype. Both families have been tested in a number of disease models in rodents.

We continue to seek to partner or out-license NAV4694. The NAV5001 sublicense was terminated in April 2015.

Tc 99m Tilmanocept – Status in Europe

The European Commission (“EC”) granted marketing authorization for Tc 99m tilmanocept in the EU in November 2014. We recently completed manufacturing validation activities on a finished drug product contract manufacturing facility to support the Company’s supply chain, primarily in Europe. This facility will produce a reduced-mass vial for which we received approval from the European Medicines Agency (“EMA”) in September 2016. Our partner, SpePharm AG (an affiliate of Norgine BV), is currently completing the customary pre-launch market access activities to support commercial launch in the EU during the first half of 2017. Following the January 2017 transfer of the Tc 99m tilmanocept Marketing Authorization to SpePharm, we are in the process of transferring responsibility for manufacturing the reduced-mass vial for the EU market to SpePharm.

Tc 99m Tilmanocept – Clinical Data and Licensing Background

In June 2016, we announced results from three investigator-initiated studies that demonstrate beneficial performance characteristics of Tc 99m tilmanocept and positive comparative results versus commonly-used, non-receptor-targeted imaging agents. The data were presented by the investigators at the 2016 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (“SNMMI”) in San Diego, CA.

“Performance of Tc-99m tilmanocept when used alone is as or more effective in localizing sentinel nodes than sulfur colloid plus blue dye,” presented by Jonathan Unkart, M.D. and Anne Wallace, M.D., Department of Surgery at UCSD, described a retrospective evaluation of the rate of localization of Tc 99m tilmanocept when used alone compared to sulfur colloid (“SC”), blue dye (“BD”) and SC plus BD. The study included results from 148 breast cancer patients evaluated in two prospective Phase 3 Tc 99m tilmanocept clinical trials (data published in *Annals of Surgical Oncology* 2013). SC and BD data was derived from a literature search presented at the SNMMI 2013 Annual Meeting including treatment groups of 17,814 SC alone, 12,821 BD alone and 19,627 SC+BD patients. Results show the following localization rates: Tc 99m tilmanocept alone: 0.9865, SC alone: 0.9249, BD alone: 0.8294 and SC+BD: 0.9636. The authors’ analysis suggests that Tc 99m tilmanocept provided superior sentinel lymph node localization in breast cancer patients compared to the other non-targeting agents alone or in combination providing surgeons the option to use just a single agent.

“Use of lymphoscintigraphy with Tc-99m tilmanocept does not affect the number of nodes removed during sentinel node biopsy (“SLNB”) in breast cancer,” also presented by Jonathan Unkart, M.D., et al, provides a retrospective review evaluating whether there is a difference in the number of nodes removed using Tc 99m tilmanocept during SLNB in patients who had a pre-operative imaging procedure called lymphoscintigraphy prior to SLNB versus those who only had intra-operative sentinel node (“SN”) identification. The results indicate that in breast cancer, identification and removal of SNs using lymphoscintigraphy (3.0 SNs) did not significantly alter the number of SNs removed during a SLNB procedure with no imaging (2.7 SNs). Tc 99m tilmanocept’s selective-targeting performance characteristic enables the utilization of only a single dose of Tc 99m tilmanocept per patient irrespective of whether both lymphoscintigraphy and SLNB are performed. The authors concluded that by using Tc 99m tilmanocept, lymphoscintigraphy imaging procedures may be eliminated in this patient population and may reduce health care cost without impacting patient outcomes.

“Rate of sentinel lymph node visualization in fatty breasts: Tc-99m Tilmanocept versus Tc-99m filtered sulfur colloid,” presented by Maryam Shahrzad, M.D. et al, describes results from a study at Emory University School of Medicine using Tc 99m tilmanocept in patients with fatty breast tissue, a population that is known to be more difficult to localize nodes when performing SLNB. The results suggest that Tc 99m tilmanocept more effectively visualized sentinel lymph nodes (“SLNs”) both on lymphoscintigraphy and during surgery compared to filtered sulfur colloids (Tc-SC) with 100% localization using Tc 99m tilmanocept intraoperatively. These retrospective data compiled from 29 consecutive patients with early stage breast cancer where lymphoscintigraphy was performed using Tc-SC and 28 patients where lymphoscintigraphy was performed using Tc 99m tilmanocept. Multiple patient variables were recorded. The Tc-SC cohort included 96% of patients with fatty breasts versus 89% in the Tc 99m tilmanocept group. Statistically significant findings included: (1) in lymphoscintigraphy, SLN visualization occurred in 86% of the Tc 99m tilmanocept group compared to 59% of the TC-SC group (*p-value*: 0.02); and (2) at surgery, 100% of patients in the Tc 99m tilmanocept group showed a “hot” SLN compared to only 79% of patients in the Tc-SC group (*p-value*: 0.01).

These data further reinforce the beneficial clinical performance attributes of Tc 99m tilmanocept. In addition, they support Tc 99m tilmanocept’s rapid adoption in sentinel lymph node biopsy procedures and its pre-surgical imaging utility for other solid tumors. We believe results from these and other performance-based studies will encourage surgeons to use Tc 99m tilmanocept as they look to optimize outcome for their patients and improve patient experience.

“Dynamics of 99mTc-tilmanocept intraoperative lymphatic mapping,” presented by Frederick Cope, Ph.D., F.A.C.N., et al, was taken from an evaluation of 38 breast cancer patients undergoing SLN mapping. These data indicated the strong correlation of macrophage presence in sentinel nodes relative to non-sentinel nodes suggesting that SLNs have a preferred biological nexus to the primary tumor site. Correlations were supported by macrophage counts, Tc 99m counts, and receptor analyses. These data further support the targeting of the CD206 receptor.

Manocept Platform - Diagnostics and Therapeutics Background

Navidea’s Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. Activated 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 serves as an engine for purpose-built molecules that may significantly impact patient care by providing enhanced diagnostic accuracy, clinical decision-making, and target-specific treatment. This disease-targeted drug platform provides the capability to utilize a breadth of diagnostic modalities, including SPECT, PET, intra-operative and/or optical-fluorescence detection, as well as delivery of therapeutic compounds that target macrophages, and their role in a variety of immune- and inflammation-based disorders. The FDA-approved sentinel node/lymphatic mapping agent, Tc 99m tilmanocept, is representative of the ability to successfully exploit this mechanism to develop powerful new products.

Impairment of the macrophage-driven disease mechanisms is an area of increasing focus in medicine. The number of people affected by all the inflammatory diseases combined is estimated at more than 40 million in the United States and perhaps 700 million worldwide, making macrophage-mediated diseases an area of remarkable clinical importance. There are many recognized disorders having macrophage involvement, including RA, atherosclerosis/vulnerable plaque, Crohn's disease, systemic lupus erythematosus, KS, and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, CNS diseases, and inflammation. Data from studies using agents from the Manocept platform in RA, KS and tuberculosis ("TB") were published in a special supplement, *Nature Outlook: Medical Imaging*, in *Nature's* October 31, 2013 issue. The supplement included a White Paper by Navidea entitled "*Innovations in receptor-targeted precision imaging at Navidea: Diagnosis up close and personal*," focused on the Manocept platform.

In July 2014, the Company completed a license agreement with UCSD for the exclusive world-wide rights in all diagnostic and therapeutic uses of tilmanocept, except for the use of Tc 99m tilmanocept in Canada, Mexico and the United States, which rights have been licensed directly to Cardinal Health 414 by UCSD in connection with the Asset Sale. The license agreement is effective until the third anniversary of the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD has granted Navidea the exclusive rights to make, use, sell, offer for sale and import licensed products for all diagnostic and therapeutic uses as defined in the agreement and to practice the defined licensed methods during the term of the agreement. Navidea may also sublicense the patent rights, subject to certain sublicense terms as defined in the agreement. In consideration for the license rights, Navidea agreed to pay UCSD a license issue fee of \$25,000 and license maintenance fees of \$25,000 per year. We also agreed to make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a \$25,000 minimum annual royalty. Navidea also agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets.

Manocept Platform – Immuno-Diagnostics Clinical Data

In April 2016, we announced that based on a meeting with the FDA, we would begin the clinical trial development process for our IV injection protocols for use of tilmanocept in RA and other disease states. Over the past year Navidea conducted a series of meetings and communications with the FDA to gain clarity on a path to extend the current Tc 99m tilmanocept investigational new drug ("IND") application to support IV administration of tilmanocept. In parallel, the Company initiated its clinical development efforts and has already completed six required non-clinical animal studies for this new route of administration, submitted the summary results in a briefing package to the FDA, and secured NIH grants in RA and KS, worth up to \$3.8 million to support further development through Phase 2 studies. Based upon the feedback from the latest meeting, Navidea expects to submit an IND amendment to the FDA that will allow initiation of Phase 1/2 IV studies of tilmanocept. The addition of this new route of administration would enable further development of tilmanocept in broader immunodiagnostic disease applications including RA, KS and CV.

Rheumatoid Arthritis

Our efforts to exploit the involvement of macrophages in the natural history of many diseases has led us through our strategy of expanding the use of tilmanocept and open new market opportunities. Importantly, one of the largest defined market opportunities resides in early diagnosis and disease monitoring for RA. RA can be difficult to detect because it may begin with subtle symptoms such as achy joints or joint stiffness especially in the morning. Further, many diseases behave like RA early on; for example, gout and lupus. There is no single test that confirms an RA diagnosis and even combinations of tests provide little specificity for RA. Current diagnostic tools such as x-rays, ultrasound and MRI fall short of being able to quantitatively measure inflammation and the underlying macrophage inflammatory component, which is a key driver of RA progression. Misdiagnosis results in billions of dollars being spent each year unnecessarily on therapies, which may also result in significant side effects.

In our primary market research, two aspects of the current unmet medical needs identified were early diagnosis and monitoring of disease progression and/or drug response. Early diagnosis and treatment improves outcomes. In patients with RA, joint damage occurs early, often within the first two years of the disease, and is irreversible. Additionally, once treatment is started, it becomes necessary to objectively monitor progression and measure how well a treatment is working or not.

Approximately 10 million patients in economically advantaged countries alone are diagnosed with RA, of which approximately half are misdiagnosed due in large part to a lack of an accurate and cost-effective means for early detection and differential diagnosis. More succinctly, our primary market research suggests that early detection alone in the U.S. could add up to 300,000 procedures per year and disease monitoring could add as many as 700,000 procedures per year.

Our goals for the use of tilmanocept in RA are:

- Reliable diagnosis of RA by imaging;
- Early differential diagnosis of RA;
- Use in monitoring patient response to RA treatments; and
- Quantitative assessment of the disease process via imaging and application to therapeutic response.

Based on our work to date, we believe we can achieve all of the diagnostic disease-managing elements with tilmanocept.

In July 2016, we received Institutional Review Board (“IRB”) approval from the University of California, San Francisco (“UCSF”) School of Medicine for a clinical study examining the ability of tilmanocept to specifically identify active RA in pre-identified RA-affected joints (ClinicalTrials.gov Identifier:NCT02683421; Study supported by NIH/NIAMSD Grant 1 R44 AR067583-01A1). Additionally, Navidea received Western Institutional Review Board (“WIRB”) approval to expand this study to other study sites at Navidea’s discretion. This study was designed as an open-label, Phase 1 clinical study of up to 18 individuals to investigate the ability of a subcutaneous injection of Tc 99m tilmanocept to identify RA inflamed joints in active RA subjects by SPECT and SPECT/CT imaging. The study has enrolled four cohorts of subjects: participants with active RA and arthritis-free individuals evaluating two different tilmanocept doses in each group. Results of this study will be used to determine tilmanocept’s ability to localize in subjects with RA and show concordance with clinical symptoms, compare the intensity between the two dose groups, and compare localization between active RA and arthritis-free subjects. Study results will provide information regarding trial design for follow-on studies. This study is complete and we are comprehensively analyzing the study data sets.

In conjunction with the agreed submission of an IND amendment for IV administration of tilmanocept to the FDA, we initiated a multi-center Phase 1/2 registrational trial employing IV administration to evaluate tilmanocept for the primary diagnosis of RA and to aid in the differential diagnosis of RA from other types of inflammatory arthritis. The first subject was dosed and imaged in February 2017. This study will enroll up to 30 subjects with dose escalation (ClinicalTrials.gov Identifier:NCT02865434; Study supported by NIH/NIAMSD Grant 1 R44 AR067583-01A1).

Cardiovascular Disease

The Company received an award for a Phase 1 SBIR grant providing \$322,000 from the National Heart Lung and Blood Institute, NIH (ClinicalTrials.gov Identifier: NCT02542371; Studies supported by NIH/NHLBI Grant 1 R43 HL127846-01). This study was conducted in collaboration with Massachusetts General Hospital and Harvard Medical School. This study is complete and examined the ability of Tc 99m tilmanocept to localize in high-risk atherosclerotic plaques. These specific plaques are rich in CD206-expressing macrophages and are at high risk for near term rupture resulting in myocardial infarctions, sudden cardiac death and strokes. The consequences of atherosclerosis and the cardiovascular disease that atherosclerosis causes, while severe in all populations of people, are particularly concentrated in human immunodeficiency virus-positive (“HIV+”) patients. Recently, it has been observed that CD206 expressing macrophages densely populate vulnerable plaques or thin cap fibroatheromas but not other kinds (i.e., calcified plaques) of atherosclerotic plaques. A primary goal for this grant involves an approved clinical investigation of up to 18 individuals with and without aortic and high risk coronary atherosclerotic plaques and with and without HIV infection to determine the feasibility of Tc 99m tilmanocept to image high risk plaque by SPECT/CT. Contrast with NaF18 was a parallel evaluation. In May 2016, we reported that the first subjects were dosed subcutaneously at Massachusetts General Hospital, and we have now completed enrollment in this study. Results were first reported at the *Conference on Retroviruses and Opportunistic Infections* by Steven Grinspoon, M.D., et al. Additional results are now published in the *Journal of Infectious Diseases* (epub - <https://doi.org/10.1093/infdis/jix095>). Results provide strong evidence of the potential of Tc 99m tilmanocept to accumulate in high risk morphology plaques, the ability to make preliminary comparisons of aortic Tc 99m tilmanocept uptake by SPECT/CT in healthy vs. clinically symptomatic patients, and to evaluate the ability of Tc 99m tilmanocept to identify the same aortic atherosclerotic plaques that are identified by contrast enhanced coronary computed tomography angiography and/or PET/CT.

Other Immuno-Diagnostic Applications

The Company has received an award for a Fast Track SBIR grant providing for up to \$1.8 million from the NIH’s National Cancer Institute to fund preclinical studies examining the safety of IV injection of Tc99m tilmanocept, a Mancept platform product, followed by a clinical study providing the initial evaluation of the safety and efficacy of SPECT imaging studies with IV Tc99m tilmanocept to identify and quantify both skin- and organ-associated KS lesions in human patients. The grant is awarded in two parts with the potential for total grant money of up to \$1.8 million over two and a half years. The first six-month funding segment of \$300,000, which has already been awarded, is expected to enable Navidea to secure necessary collaborations and Institutional Review Board approvals. The second funding segment could provide for up to an additional \$1.5 million to be used to accrue participants, perform the Phase 1/2 study and perform data analyses to confirm the safety and effectiveness of intravenously administered Tc99m tilmanocept. We have received IRB approval of the clinical protocol, and we plan to initiate a Phase 1/2 clinical study in KS during 2017.

Our commercial evaluation of new clinical data as well as our evolving understanding of Tc 99m tilmanocept, the underlying Manocept backbone, and its potential utility in identifying tumor-associated macrophages (“TAMs”) and multifocal tumor disease have caused us to question the viability of the NAV1800 development program (previously referred to as the RIGS® or radioimmunoguided surgery program) as it was originally envisioned. To that end, we petitioned the NIH to repurpose the \$1.5 million grant we were previously awarded towards the study of TAMs in colorectal cancer, and subsequently received confirmation of the acceptance of this repurposing. This repurposed grant now supports a Manocept-based diagnostic approach in patients with anal/rectal cancer and possibly colon cancer. We recognize this repurposing represents a major refocusing of the original NAV1800 initiative, but we are confident that this change represents the best course of action at this time towards benefiting patients afflicted with colorectal cancer and is one which is consistent with the excitement we are seeing on many fronts related to our work on the Manocept platform. To this end, we have completed two preclinical evaluations, clinical trial protocol development, and site review; we are awaiting IRB confirmation for the clinical portion of this initiative. However, there can be no assurance that if further clinical trials for this product 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.

Macrophage Therapeutics Background

In December 2014, the Company formed a new business unit, Macrophage Therapeutics, to further explore therapeutic applications for the Manocept platform. In January 2015, Navidea incorporated the business unit as Macrophage Therapeutics, Inc. (“MT”), initially a wholly-owned subsidiary of Navidea.

In March 2015, MT entered into a Securities Purchase Agreement to sell up to 50 shares of its Series A Convertible Preferred Stock (“MT Preferred Stock”) and warrants to purchase up to an additional 1,500 common shares of Macrophage Therapeutics, Inc. (“MT Common Stock”) to Platinum-Montaur Life Sciences, LLC (together with its affiliates, “Platinum”) and Dr. Michael Goldberg, then one of our directors and CEO of Macrophage Therapeutics, Inc. (collectively, the “MT Investors”); the agreed purchase price was \$50,000 per unit. On March 13, 2015, Navidea announced that definitive agreements with the MT Investors had been signed for the sale of the first 10 shares of MT Preferred Stock and warrants to purchase 300 shares of MT Common Stock to the MT Investors, with gross proceeds to MT of \$500,000. Under the agreement, 40% of the MT Preferred Stock and warrants are committed to be purchased by Dr. Goldberg, and the balance by Platinum. The full 50 shares of MT Preferred Stock and warrants that may be sold under the agreement are convertible into and exercisable for MT Common Stock representing an aggregate 1% interest on a fully converted and exercised basis. Navidea retains ownership of the remainder of MT Common Stock.

In addition, Navidea entered into a Securities Exchange Agreement with the MT Investors providing them an option to exchange their MT Preferred Stock for our common stock in the event that MT has not completed a public offering with gross proceeds to MT of at least \$50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing \$50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our common stock on the second anniversary of the initial closing or (ii) \$3.00. To the extent that the MT Investors do not timely exercise their exchange right, MT has the right to redeem their MT Preferred Stock for a price equal to \$58,320 per share. Navidea also granted MT an exclusive license for certain therapeutic applications of the Manocept technology.

MT has developed processes for producing the first two therapeutic Manocept immunoconstruct classes, MT-1000, designed to specifically target and kill activated CD206+ macrophages and MT-2000, designed to inhibit the inflammatory activity of activated CD206+ macrophages. The first of these constructs are MT-1001 and MT-2001, both developed from the Manocept platform technology and the efforts of Navidea’s development team and contain a similar chemical scaffold and targeting moieties designed to selectively target CD206+ macrophages. A payload of a select therapeutic molecule is conjugated to each immunoconstruct through a linkage that will release the molecule within the targeted tissue: MT-1001 contains doxorubicin moieties (an anthracycline antitumor antibiotic), conjugated to the Manocept backbone while MT-2001 contains a potent anti-inflammatory agent. MT has contracted with independent facilities to produce sufficient quantities of the MT-1000 and MT-2000 class agents along with the concomitant analytical standards, to provide material for planned preclinical animal studies and future clinical trial.

Manocept Platform – Immunotherapeutics In-Vitro and Pre-Clinical Data

During investor update conference calls held during 2016, MT reported the following from its ongoing pre-clinical animal studies:

- Binding affinity studies with the therapeutic constructs confirm results seen with imaging agent with dissociation constants (K_d) on the order of 10^{-11} ;
 - Cell culture studies with numerous infectious agents demonstrate consistent activity across all agents tested including HIV, human herpesvirus 8 (“HHV8”), Zika, leishmaniasis, and dengue;
 - An 8-week, preclinical mouse study in an arthritis mouse model with a Manocept anti-inflammatory targeted therapeutic product, MT2002, was completed with initial results reporting clear anti-inflammatory activity with no apparent significant side-effects;
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- An animal study in an asthma model that measured the ability of MT2002 to decrease all three markers of pro-inflammatory markers secreted by disease-causing macrophages was completed and successfully demonstrated an anti-inflammatory effect;
- A study in a rodent neuro-inflammation model confirmed the ability to cross the blood-brain barrier while maintaining the desired activity of the therapeutic linked to our delivery agent;
- We completed three studies in an animal model for non-alcoholic steatohepatitis (“NASH”). We have looked at a number of different dosing regimens and compared performance of both families of our therapeutic products. We have also looked at initiating dosing later in the course of the disease to determine if we can have an impact on preventing fibrosis. According to the group that ran these studies (Stelic, Japan), our agents performed the best of all agents they have ever tested in their STAM™ animal model. Finally, the livers of these animals were analyzed and showed no evidence of off-target or histopathological damage.
- We completed dosing in a neuro-inflammation model which confirmed that the anti-inflammatory construct very effectively crosses the blood-brain barrier. This study also confirmed that the addition of the drug conjugate to the Manocept backbone did not affect blood-brain barrier activity.
- We completed four independent cancer-modeling studies evaluating the TAM-depleting performance of compounds from the MT1000 class of conjugates. In three of these models employing the MT1000 conjugate alone, we observed an immediate reduction on the rate of tumor growth. In a fourth cancer model where the MT agent was tested in combination with a tumor targeted antibody we also observed a significant co-effect on tumor reduction. This latter study was repeated and further highlighted the potentiation of the targeted antibody to the tumor driven by the MT agent targeting to the TAMs, a key component of the tumor microenvironment.

The novel Manocept construct is designed to specifically deliver doxorubicin, a chemotoxin, which can kill KS tumor cells and their TAMs potentially altering the course of cancer. KS is a serious and potentially life threatening illness in persons infected with HIV and the third leading cause of death in this population worldwide. The prognosis for patients with KS is poor with high probabilities for mortality and greatly diminished quality of life. The funds for this Fast Track grant will be released in three parts, which together have the potential to provide up to \$1.8 million in resources over 2.5 years with the goal of completing an IND submission for a Manocept construct (MT1000 class of compounds) consisting of tilmanocept linked to doxorubicin for the treatment of KS. The first part of the grant will provide \$232,000 to support analyses including in vitro and cell culture studies and will be followed by Part 2 and 3 animal testing studies. If successful, the information from these studies will be combined with other information in an IND application that will be submitted to the FDA requesting permission to begin testing the compound selected in human KS patients.

Navidea and MT continue to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform, including ongoing studies in KS and RA. The immuno-inflammatory process is remarkably complex and tightly regulated with indicators that initiate, maintain and shut down the process. Macrophages are immune cells that play a critical role in the initiation, maintenance, and resolution of inflammation. They are activated and deactivated in the inflammatory process. Because macrophages may promote dysregulation that accelerates or enhances disease progression, diagnostic and therapeutic interventions that target macrophages may open new avenues for controlling inflammatory diseases. There can be no assurance 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 (Candidate for Divestiture)

NAV4694 is a fluorine-18 (“F-18”) labeled PET imaging agent being developed as an aid in the imaging and evaluation of patients with signs or symptoms of Alzheimer’s disease (“AD”) and mild cognitive impairment (“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. NAV4694 has been studied in rigorous pre-clinical studies and clinical trials in humans. Clinical studies through Phase 3 have included subjects with 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.

In May 2014, the Board of Directors made the decision to refocus the Company's resources to better align the funding of our pipeline programs with the expected growth in Tc 99m tilmanocept revenue. This realignment primarily involved reducing our near-term support for our neurological product candidates, including NAV4694, as we sought a development partner or partners for these programs. The Company is currently engaged in discussions related to the potential partnering or divestiture of NAV4694. We continue to have active interest from potential partners or acquirers; however, our negotiations have experienced delays due in large part to litigation brought by one of the potential partners (see Part II, Item 1 – Legal Proceedings). The Company believed the suit was without merit and filed a motion to dismiss the action. In September 2016, the court determined that there was enough evidence to proceed with the case and denied Navidea's motion to dismiss. Navidea is currently preparing for a trial which is expected to take place within the next twelve months. At this time it is not possible to determine with any degree of certainty the ultimate outcome of this legal proceeding, including making a determination of liability.

In July 2016, the Company executed a term sheet with Cerveau Technologies, Inc. ("Cerveau") as a designated party for the rights resulting from the relationship between Navidea and Hainan Sinotau Pharmaceutical Co., Ltd. ("Sinotau"). The term sheet outlined the terms of a potential agreement between the parties to sublicense NAV4694 to Cerveau in return for license fees, milestone payments and royalties. With the exception of certain provisions, the term sheet was non-binding and was subject to the agreement of AstraZeneca, from whom the Company has licensed the NAV4694 technology. The Company had 60 days to execute a definitive agreement, however no definitive agreement was reached. Discussions related to the potential partnering or divestiture of NAV4694 are ongoing.

NAV5001 (In-License Terminated)

NAV5001 is an iodine-123 ("I-123") labeled 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. 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. 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, one of the most common forms of dementia after AD.

In May 2014, the Board of Directors made the decision to refocus the Company's resources to better align the funding of our pipeline programs with the expected growth in Tc 99m tilmanocept revenue. This realignment primarily involved reducing our near-term support for our neurological product candidates, including NAV5001.

In April 2015, the Company entered into an agreement with Alseres to terminate the sub-license agreement dated July 31, 2012 for research, development and commercialization of NAV5001. Under the terms of this agreement, Navidea transferred all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres agreed to reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, Navidea has supplied clinical support services for NAV5001 on a cost-plus reimbursement basis. However, to this point, Alseres has been unsuccessful in raising the funds necessary to restart the program and reimburse Navidea. As a result, we have taken steps to end our obligations under the agreement and notified Alseres that we consider them in breach of the agreement. We are in the process of trying to recover the funds we expended complying with our obligations under the termination agreement. As of the filing of this document, we remain in discussions and Alseres has expressed its commitment to pay the related payables.

Market Overviews

Tc 99m Tilmanocept – Cancer Market Overview

Cancer is the second leading cause of death in the U.S. and the leading cause of death in 12 European countries. The American Cancer Society ("ACS") estimates that cancer will cause over 600,000 deaths in 2017 in the U.S. alone. The Agency for Healthcare Research and Quality has estimated that the direct medical costs for cancer in the U.S. for 2014 were \$87.8 billion. Additionally, the ACS estimates that approximately 1.7 million new cancer cases will be diagnosed in the U.S. during 2017. 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 over 1.1 million new cases will occur in the U.S. in 2017.

Currently, the application of intraoperative lymphatic mapping ("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 6.8% in women age 70 or older. According to the ACS, over 255,000 new cases of breast cancer are expected to be diagnosed during 2017 in the U.S. alone.

The use of ILM is also common in melanoma. The ACS estimates that approximately 87,000 new cases of melanoma will be diagnosed in the U.S. during 2017. In addition to breast cancer and melanoma, we believe that our oncology products may have utility in other cancer types with another 786,000 new cases expected during 2017 in the U.S.

If the potential of Tc 99m tilmanocept as a radioactive tracing agent is ultimately realized, it may address not only the 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, gynecologic, and non-small cell lung. Tc 99m tilmanocept is approved by the U.S. FDA for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Tc 99m tilmanocept has also received European approval in imaging and intraoperative detection of sentinel lymph nodes in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Manocept Diagnostics and Macrophage Therapeutics Market Overview

Impairment of the macrophage-driven disease mechanism is an area of increasing focus in medicine. The number of people affected by all the inflammatory diseases combined is estimated at more than 40 million in the United States and perhaps 700 million worldwide, making these macrophage-mediated diseases an area of remarkable clinical importance. There are many recognized disorders having macrophage involvement, including RA, atherosclerosis/vulnerable plaque, Crohn's disease, TB, systemic lupus erythematosus, KS, and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, and inflammation. Data from studies using agents from the Manocept platform in RA, KS and TB were published in a special supplement, *Nature Outlook: Medical Imaging*, in *Nature's* October 31, 2013 issue. The supplement included a White Paper by Navidea entitled "*Innovations in receptor-targeted precision imaging at Navidea: Diagnosis up close and personal*," focused on the Manocept platform.

NAV4694 - Alzheimer's Disease Market Overview

The Alzheimer's Association ("AA") estimates that more than 5.4 million Americans had AD in 2016. On a global basis, Alzheimer's Disease International estimated in 2015 that there were 46.8 million people living with dementia. AA estimates that total costs for AD care was approximately \$236 billion in 2016 and is expected to rise to more than \$1 trillion by 2050. AA also estimates that there are over 15 million AD and dementia caregivers providing 18.1 billion hours of unpaid care valued at over \$221 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 U.S. mortality data from 2000-2013, deaths from AD have risen 71 percent while deaths attributed to the number one cause of death, heart disease, decreased 14 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.

Marketing and Distribution

In March 2017, Navidea completed the Asset Sale to Cardinal Health 414, as discussed previously under "Development of the Business." Pursuant to the Purchase Agreement, we sold all of our assets used, held for use, or intended to be used in operating the Business, including the Product, in the Territory. Upon closing of the Asset Sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated and Cardinal Health 414 has assumed responsibility for marketing Lymphoseek in the Territory.

Unlike the U.S., where institutions typically rely on radiopharmaceutical products which are compounded and delivered by specialized radiopharmacy distributors such as Cardinal Health 414, institutions in Europe predominantly purchase non-radiolabeled material and compound the radioactive product on-site. With respect to Tc 99m tilmanocept commercialization in Europe, we have chosen a specialty pharmaceutical strategy that should be supportive of premium product positioning and reinforce Tc 99m tilmanocept's clinical value proposition, as opposed to a commodity or a generics positioning approach. In March 2015, we entered into an exclusive sublicense agreement for the commercialization and distribution of a 50 microgram kit for radiopharmaceutical preparation (tilmanocept) in the European Union with SpePharm AG (an affiliate of Norgine BV), a European specialist pharmaceutical company with an extensive pan-European presence. Under the terms of the exclusive license agreement, Navidea transferred responsibility for regulatory maintenance of the Tc 99m tilmanocept Marketing Authorization to SpePharm in January 2017. SpePharm will also be responsible for production, distribution, pricing, reimbursement, sales, marketing, medical affairs, and regulatory activities. In connection with entering into the agreement, Navidea received an upfront payment of \$2 million, and is entitled to milestones totaling up to an additional \$5 million and royalties on European net sales. The initial territory covered by the agreement includes all 28 member states of the European Economic Community with the option to expand into additional geographical areas. SpePharm is currently performing the customary pre-launch market access activities to support commercial launch in the EU during the first half of 2017.

In August 2014, Navidea entered into an exclusive agreement with Sinotau, a pharmaceutical organization with a broad China focus in oncology and other therapeutic areas, who will develop and commercialize Tc 99m tilmanocept in China. In exchange, Navidea will earn revenue based on unit sales to Sinotau, a royalty based on Sinotau's sales of Tc 99m tilmanocept and up to \$2.5 million in milestone payments from Sinotau, including a \$300,000 non-refundable upfront payment. As part of the agreement, Sinotau is responsible for costs and conduct of clinical studies and regulatory applications to obtain Tc 99m tilmanocept approval by the China Food and Drug Administration (CFDA). Upon approval, Sinotau will be responsible for all Tc 99m tilmanocept sales, marketing, market access and medical affairs activities in China and excluding Hong Kong, Macau and Taiwan. Navidea and Sinotau will jointly support certain pre-market planning activities with a joint commitment on clinical and market development programs pending CFDA approval. In addition to the \$300,000 upfront payment, Navidea is eligible for \$700,000 in milestone payments up to and through product approval, and an additional \$1.5 million in sales milestones. On February 1, 2017, Navidea filed a suit against Sinotau, and on February 2, 2017, Sinotau filed a suit against the Company and Cardinal Health 414. See Item 3 – Legal Proceedings.

Tc 99m tilmanocept is in various stages of approval in other global markets and sales to this point in these markets, if any, have not been material. However, we believe that with international partnerships to complement our position in the EU, we will help establish Tc 99m tilmanocept as a global leader in lymphatic mapping, as we are aware of no other company which has a global geographic range. We cannot assure you that Tc 99m tilmanocept will achieve regulatory approval in any market outside the U.S. or EU, or if approved, that it will achieve market acceptance in any market. We also 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. See Risk Factors.

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 may 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.

Tc 99m Tilmanocept Manufacturing

In November 2009, we completed a Manufacture and Supply Agreement with Reliable Biopharmaceutical Corporation (“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 OSO BioPharmaceuticals Manufacturing, LLC (“OsoBio”) for contract pharmaceutical development, manufacturing, packaging and analytical services for Tc 99m tilmanocept. Also in September 2013, we completed a Service and Supply Master Agreement with Gipharma S.r.l. (“Gipharma”) for process development, manufacturing and packaging of reduced-mass vials for sale in the EU. Upon closing of the Asset Sale to Cardinal Health 414, our contracts with Reliable and OsoBio were transferred to Cardinal Health 414. Similarly, following the transfer of the Tc 99m tilmanocept Marketing Authorization to SpePharm, our contract with Gipharma will be transferred to SpePharm. We cannot assure you that we will be successful in completing future agreements for the supply of Tc 99m tilmanocept 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 manufactured NAV4694 clinical trial material at select U.S. radiopharmacies through the expiration of the agreement in August 2016. Navidea has continued to incur costs related to maintaining our NAV4694 manufacturing sites while seeking to partner or out-license the product.

Summary

We cannot assure you that we will be successful in securing and/or maintaining the necessary manufacturing, supply and/or radiolabeling capabilities for our product candidates in clinical development. If and when established, we also cannot assure you that we will be able to maintain agreements or other purchasing arrangements with our subcontractors on terms acceptable to us, or that our subcontractors will be able to meet our production requirements on a timely basis, at the required levels of performance and quality, 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.

We expect to encounter significant competition for our pharmaceutical products. 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 expect that competition among products cleared for marketing will be based on, among other things, product efficacy, safety, reliability, availability, price, and patent position. See Risk Factors.

Tc 99m Tilmanocept Competition

Surgeons who practice the lymphatic mapping procedure for which Tc 99m tilmanocept is intended currently use other radiopharmaceuticals such as a sulfur colloid or other colloidal compounds. In addition, some surgeons still use vital blue dyes to assist in the visual identification of the draining lymphatic tissue around a primary tumor. In the EU and certain Pacific Rim markets, there are colloidal-based compounds with various levels of approved labeling for use in lymphatic mapping, although a number of countries still employ products used “off-label.”

NAV4694 Competition

Several potential competitive [¹⁸F] products have been approved for use as biomarkers to aid in detection of AD. Developed through Eli Lilly’s wholly-owned Avid Radiopharmaceuticals, florbetapir, now known as Amyvid, received FDA approval to market in April 2012. Florbetapir also received marketing authorization in the EU in January 2013. In addition to fluorbetapir, there are two other beta-amyloid imaging agents available: florbetaben from Piramal Enterprises, Imaging Division, and flutemetamol from GE Healthcare. In October 2013, the FDA approved flutemetamol, under the name Vizamyli™, for adults being evaluated for AD and dementia with PET brain imaging. Florbetaben, now called Neuraceq™, received EMA approval for use in PET imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for AD and other causes of cognitive decline from the EMA in February 2014 and from the FDA in March 2014.

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 the 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. See Risk Factors.

Tilmanocept Intellectual Property

Tilmanocept is under license from UCSD for the exclusive world-wide rights in all diagnostic and therapeutic uses of tilmanocept, except for the use of Tc 99m tilmanocept in Canada, Mexico and the United States, which rights have been licensed directly to Cardinal Health 414 by UCSD in connection with the Asset Sale. Navidea maintains license rights to Tc 99m tilmanocept in the rest of the world, as well as a license to the intellectual property underlying the Manocept platform.

Tc 99m tilmanocept, including the Manocept backbone composition and methods of use, is the subject of multiple patent families totaling 42 patents and patent applications in the United States and certain major foreign markets.

The first composition of matter patent covering tilmanocept was issued in the United States in June 2002. This patent will expire in May 2020, but a request for patent term extension has been filed to further extend the life of this patent. The claims of the composition of matter patent covering tilmanocept have been allowed in the EU and issued in the majority of major-market EU countries in 2004. These patents will expire in 2020, but a request for supplemental protection certificates are in process to further extend the life of these patents. The composition of matter patent has also been issued in Japan, which will expire in 2020.

We have filed additional patent applications in the U.S. and certain major foreign markets related to manufacturing processes for tilmanocept, the first of which was issued in the U.S. in 2013. These patents and/or applications will expire between 2029 and 2032. We have filed further patent applications jointly with The Ohio State Innovation Foundation related to CD206 expressing cell-related disorders. These patents and/or applications will expire between 2034 and 2035. We have filed further patent applications related to 2-heteroaryl substituted benzofurans. These patents and/or applications will expire between 2036 and 2037.

We will also rely on trademark protection for products that we expect to commercialize and have registered or are in the process of registering the mark Manocept™ in the U.S. and other markets.

NAV4694 Intellectual Property

NAV4694 is being developed under an exclusive worldwide license from AstraZeneca. The NAV4694 license grants Navidea commercialization rights to the fluorine-18 labeled biomarker for use as an aid in the diagnosis of AD. NAV4694 is the subject of 3 issued patents in the U.S. and 29 patents issued or pending in 13 foreign jurisdictions covering the [¹⁸F]NAV4694 drug substance and the NAV4694 precursor. These patents and/or applications will expire between 2028 and 2029.

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 U.S. 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 application 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 a 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 Special Protocol Assessment (“SPA”). These agreements may not be changed after the clinical studies begin, except in limited circumstances. The existence of a SPA, however, does not assure approval of a product candidate.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacturing quality and composition of the investigational product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort and financial resources. Submission of an NDA requires payment of a substantial review user fee to the FDA. Before approving a NDA, the FDA usually will inspect the facility or the facilities where the product is manufactured, tested and distributed and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA may issue an approval letter or a complete response letter. A complete response letter outlines conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA’s satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of approval, the FDA may require post-marketing testing and surveillance to monitor the product’s safety or efficacy, or impose other post-approval commitment conditions.

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

U.S. 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.

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. A mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure.

The EC granted marketing authorization for Tc 99m tilmanocept in the EU in November 2014, and a reduced-mass vial developed for the EU market was approved in September 2016.

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 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” and the Navidea logo 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-39 of this Form 10-K.

Research and Development

We spent approximately \$8.9 million, \$12.8 million and \$16.8 million on research and development activities in the years ended December 31, 2016, 2015 and 2014, respectively.

Employees

As of March 10, 2017, we had 22 full-time and 6 part-time employees.

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 Form 10-K, 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 Cardinal Health 414 or SpePharm AG do not achieve commercial success with Tc 99m tilmanocept, we may be unable to generate significant revenue or become profitable.

In March 2017, Navidea completed the Asset Sale to Cardinal Health 414, as discussed previously under “Development of the Business.” Pursuant to the Purchase Agreement, we sold all of our assets used, held for use, or intended to be used in operating the Business, including Lymphoseek, in Canada, Mexico and the United States. Upon closing of the Asset Sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated. Under the terms of the Purchase Agreement, Navidea is entitled to receive periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) from Cardinal Health 414 based on net sales derived from Lymphoseek, subject, in each case, to Cardinal Health 414’s right to off-set.

We announced an exclusive EU distribution partnership for Tc 99m tilmanocept with SpePharm AG, a subsidiary of Norgine B.V., in March 2015, and SpePharm expects to commence marketing of Tc 99m tilmanocept in the EU during the first half of 2017. Navidea is entitled to receive royalty and milestone payments from SpePharm based on net sales derived from Tc 99m tilmanocept.

We cannot assure you that Cardinal Health 414 or SpePharm will achieve commercial success in North America or in the EU, or any other global market, that Cardinal Health 414 or SpePharm will realize sales at levels necessary for us to achieve sales-based earnout, royalty or milestone payments, or that such payments will lead to us becoming profitable.

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

Additional diagnostic and therapeutic applications of the Manocept platform, including diagnosis of other solid tumor cancers, rheumatoid arthritis and cardiovascular disease, are in various stages of pre-clinical and clinical development. Regulatory approval of additional Manocept-based product candidates may not be successful, or if successful, may not result in increased sales. Additional clinical testing for 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.

We are continuing to seek to partner or sub-license our NAV4694 candidate, which is designed to enable PET imaging of beta-amyloid deposits in the brain, believed to correlate with the presence of AD. While discussions with a potential licensee have progressed, our pending litigation with Sinotau has prevented completion of a licensing transaction. See Item 3 – Legal Proceedings. Pending resolution of the Sinotau litigation, we continue to incur costs to maintain our ability to support future clinical evaluation of this product candidate to preserve it for eventual sub-licensing.

Many companies in the pharmaceutical industry suffer significant setbacks in advanced clinical trials even after reporting promising results in earlier trials. Even if our Manocept trials are viewed as successful, we may not get regulatory approval for marketing of any Manocept product candidate. Our Manocept 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 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.

Clinical trials for our 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.

We expect to sponsor efforts to explore the Manocept platform, whether in potential diagnostic or therapeutic uses. 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, the EMA or other regulatory authorities 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 Tc 99m tilmanocept as indicated by the FDA and EMA approvals, the results of pending and future trials for 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.

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

We have dedicated and will continue to dedicate substantially all of our resources to the research and development (R&D) of our Manocept technology and related compounds. There are many difficulties and uncertainties inherent in pharmaceutical R&D and the introduction of new products. A high rate of failure is inherent in new drug discovery and development. The process to bring a drug from the discovery phase to regulatory approval can take 12 to 15 years or longer and cost more than \$1 billion. Failure can occur at any point in the process, including late in the process after substantial investment. As a result, most research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success. Delays and uncertainties in the regulatory approval processes in the US and in other countries can result in delays in product launches and lost market opportunities. Consequently, it is very difficult to predict which products will ultimately be approved. Due to the risks and uncertainties involved in the R&D process, we cannot reliably estimate the nature, timing, completion dates, and costs of the efforts necessary to complete the development of our R&D projects, nor can we reliably estimate the future potential revenue that will be generated from a successful R&D project.

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 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 have entered 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.

Our pharmaceutical 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.

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”). Generally, in Europe and other countries outside the U.S., the government-sponsored healthcare system is the primary payer of patients’ healthcare costs. 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.

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 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. 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, clinical trials for our 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.

Our product supply and related patient access could be negatively impacted by, among other things: (i) product seizures or recalls or forced closings of manufacturing plants; (ii) disruption in supply chain continuity including from natural or man-made disasters at a critical supplier, as well as our failure or the failure of any of our suppliers to comply with cGMPs and other applicable regulations or quality assurance guidelines that could lead to manufacturing shutdowns, product shortages or delays in product manufacturing; (iii) manufacturing, quality assurance/quality control, supply problems or governmental approval delays; (iv) the failure of a sole source or single source supplier to provide us with the necessary raw materials, supplies or finished goods within a reasonable timeframe; (v) the failure of a third-party manufacturer to supply us with bulk active or finished product on time; and (vi) other manufacturing or distribution issues, including limits to manufacturing capacity due to regulatory requirements, and changes in the types of products produced, physical limitations or other business interruptions.

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

The biotech and pharmaceutical industries are intensely competitive. Many of our competitors have significantly greater financial, technical, manufacturing, marketing and distribution resources as well as greater experience in the 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.

To remain competitive, we must continue to launch new products and technologies. To accomplish this, we commit substantial efforts, funds, and other resources to research and development. A high rate of failure is inherent in the research and development of new products and technologies. We must make ongoing substantial expenditures without any assurance that our efforts will be commercially successful. Failure can occur at any point in the process, including after significant funds have been invested. Promising new product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or infringement of the intellectual property rights of others. Even if we successfully develop new products or enhancements or new generations of our existing products, they may be quickly rendered obsolete by changing customer preferences, changing industry standards, or competitors' innovations. Innovations may not be accepted quickly in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire compounds or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, causing our revenues and operating results to suffer.

Physicians may use our competitors' products and/or our products may not be competitive with other technologies. Tc 99m tilmanocept is expected to continue to compete against sulfur colloid in the U.S. and other colloidal agents in the EU and other global markets. If our competitors are successful in establishing and maintaining market share for their products, our future earnout and royalty receipts may not occur at the rate we anticipate. In addition, our 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.

Several pharmaceutical companies currently have product candidates in development that they expect to have a significant impact on the diagnosis and treatment of AD in coming years. The prospects for these product candidates could have a significant impact, either positive or negative, on our ability to sub-license our NAV4694 product candidate.

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 any commercial products that we develop, 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 our Manocept platform 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 our Manocept platform, upon which all of our current product candidates are based. 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 three to twenty 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.

We and our collaborators 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 Manocept and NAV4694, we have 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 Manocept licenses, and have had limited control over the filing and prosecution of these patents and patent applications after the effective date of such licenses. 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 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 licensors 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.

We may be unable to complete partnering or divestiture activities related to NAV4694 at a reasonable price, on a timely basis, or at all.

We have announced that we are seeking to partner or sub-license our NAV4694 candidate, which is designed to enable PET imaging of beta-amyloid deposits in the brain, believed to correlate with the presence of AD. While discussions with a potential licensee have progressed, our pending litigation with Sinotau has prevented completion of a licensing transaction. See Item 3 – Legal Proceedings. Pending resolution of the Sinotau litigation, we continue to incur costs to maintain our ability to support future clinical evaluation of this product candidate to preserve it for eventual sub-licensing.

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 do not currently carry cyber risk insurance.

We are subject to domestic and foreign anticorruption laws, the violation of which could expose us to liability, and cause our business and reputation to suffer.

We are subject to the U.S. Foreign Corrupt Practices Act and similar anti-corruption laws in other jurisdictions. These laws generally prohibit companies and their intermediaries from engaging in bribery or making other prohibited payments to government officials for the purpose of obtaining or retaining business, and some have record keeping requirements. The failure to comply with these laws could result in substantial criminal and/or monetary penalties. We operate in jurisdictions that have experienced corruption, bribery, pay-offs and other similar practices from time-to-time and, in certain circumstances, such practices may be local custom. We have implemented internal control policies and procedures that mandate compliance with these anti-corruption laws. However, we cannot be certain that these policies and procedures will protect us against liability. There can be no assurance that our employees or other agents will not engage in such conduct for which we might be held responsible. If our employees or agents are found to have engaged in such practices, we could suffer severe criminal or civil penalties and other consequences that could have a material adverse effect on our business, financial position, results of operations and/or cash flow, and the market value of our common stock could decline.

Our international operations expose us to economic, legal, regulatory and currency risks.

Our operations extend to countries outside the United States, and are subject to the risks inherent in conducting business globally and under the laws, regulations, and customs of various jurisdictions. These risks include, but are not limited to: (i) compliance with a variety of national and local laws of countries in which we do business, including but not limited to restrictions on the import and export of certain intermediates, drugs, and technologies, (ii) compliance with a variety of US laws including, but not limited to, the Iran Threat Reduction and Syria Human Rights Act of 2012; and rules relating to the use of certain “conflict minerals” under Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) changes in laws, regulations, and practices affecting the pharmaceutical industry and the health care system, including but not limited to imports, exports, manufacturing, quality, cost, pricing, reimbursement, approval, inspection, and delivery of health care, (iv) fluctuations in exchange rates for transactions conducted in currencies other than the functional currency, (v) adverse changes in the economies in which we or our partners and suppliers operate as a result of a slowdown in overall growth, a change in government or economic policies, or financial, political, or social change or instability in such countries that affects the markets in which we operate, particularly emerging markets, (vi) differing local product preferences and product requirements, (vii) changes in employment laws, wage increases, or rising inflation in the countries in which we or our partners and suppliers operate, (viii) supply disruptions, and increases in energy and transportation costs, (ix) natural disasters, including droughts, floods, and earthquakes in the countries in which we operate, (x) local disturbances, terrorist attacks, riots, social disruption, or regional hostilities in the countries in which we or our partners and suppliers operate and (xi) government uncertainty, including as a result of new or changed laws and regulations. We also face the risk that some of our competitors have more experience with operations in such countries or with international operations generally and may be able to manage unexpected crises more easily. Furthermore, whether due to language, cultural or other differences, public and other statements that we make may be misinterpreted, misconstrued, or taken out of context in different jurisdictions. Moreover, the internal political stability of, or the relationship between, any country or countries where we conduct business operations may deteriorate. Changes in a country’s political stability or the state of relations between any such countries are difficult to predict and could adversely affect our operations, profitability and/or adversely impact our ability to do business there. The occurrence of any of the above risks could have a material adverse effect on our business, financial position, results of operations and/or cash flow, and could cause the market value of our common stock to decline.

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 potentially to acquire new product candidates. In order to support the initiatives envisioned in our business plan, we will likely 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 may need to expand our workforce to pursue our business plan, and the costs involved in recruiting, training, compensating 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.

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 warrants or other securities convertible into or exchangeable for our common stock, or securities we may issue in the future, 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 could decline as a result of sales of a large number of shares of our common stock or other securities in the market, the triggering of any such adjustment provisions or the perception that such sales could occur in the future.

The final outcome of the Texas CRG litigation may require us to pay up to an additional \$7 million, which would adversely affect our financial position.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of \$4.1 million that was on deposit, applying \$3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining \$189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million (the "Deposit Amount") of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents (the "Final Payoff Amount"). The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million (the "Low Payoff Amount") and no more than \$66 million (the "High Payoff Amount"). In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to

the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The Company and CRG also agreed that the \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case would be released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7 million letter of credit, and on March 7, 2017, CRG posted a \$12 million letter of credit, each as required by the Global Settlement Agreement. The Texas hearing is currently set for July 3, 2017.

If we are ultimately required to pay an additional \$7 million to CRG, such payment would have a significant adverse effect on our financial position and would likely force us to curtail our planned development activities.

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

Shares of our common stock are common equity interests. This means that our common stock ranks junior to 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 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 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, 2016, the Company had a stockholders' deficit of approximately \$67.7 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 NYSE MKT Company Guide also provides that the Exchange may suspend or remove from listing any common stock selling for a substantial period of time at a low price per share, if the issuer shall fail to effect a reverse split of such shares within a reasonable time after being notified that the Exchange deems such action to be appropriate under all the circumstances. The Company's common stock has recently traded for a price as low as \$0.29 per share, and if the low trading price persists, there is a risk that the Exchange may require the Company to effect a reverse split of its common stock in order to maintain its NYSE MKT listing, and that the shares will be delisted if such action is not taken to the satisfaction of the NYSE MKT.

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 \$0.26 per share and as high as \$1.51 per share during the 12-month period ended February 28, 2017. 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, 2016 and ending on February 28, 2017, the average daily trading volume for our common stock on the NYSE MKT was approximately 1.2 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.

Our management and our independent auditors have identified certain internal control deficiencies, which management and our independent auditors believe constitute material weaknesses although they did not result in any adjustments.

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. It was 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.

Our management's evaluation of the effectiveness of the Company's internal controls over financial reporting as of December 31, 2016 concluded that our controls were not effective, due to material weaknesses resulting from:

- The Company did not maintain adequate controls to ensure that information pertinent to the Company's operations were analyzed and communicated by and between financial and non-financial management personnel of the Company. Management has concluded that this control deficiency represented a material weakness.
- The Company did not maintain effective oversight of the Company's external financial reporting and internal control over financial reporting by the Company's audit committee. Management has concluded that this control deficiency represented a material weakness.

Management believes there is a reasonable possibility that these control deficiencies, if uncorrected, could result in material misstatements in the annual or interim consolidated financial statements that would not be prevented or detected in a timely manner. Accordingly, we have determined that these control deficiencies constitute material weaknesses. However, notwithstanding these material weaknesses, management has concluded that the consolidated financial statements included in this Report fairly present, in all material respects, the Company's consolidated financial position, results of operations and cash flows for the periods presented therein, in conformity with accounting principles generally accepted in the United States of America. Although the Company is taking steps to remediate the material weaknesses, there can be no assurance that similar incidents can be prevented in the future if the internal controls are not followed by senior management and our Board of Directors. See Controls and Procedures—Disclosure Controls and Procedures.

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 \$25,000 during 2017. We must also pay a pro-rata portion of the operating expenses and real estate taxes of the building. We also lease approximately 2,000 square feet of office space at 560 Sylvan Avenue, Englewood Cliffs, New Jersey. The current lease term expires in March 2018, at a monthly base rent of approximately \$3,000. We must also pay a pro-rata portion of the electricity costs of the building. The New Jersey office is primarily for the use of Dr. Goldberg and Mr. Latkin and the planned hires in business and corporate development for both Navidea and Macrophage Therapeutics. We believe that this location will improve our access to qualified candidates, as it is located in close proximity to the headquarters of many large pharmaceutical companies which are located in New York City and New Jersey. It also places our senior management closer to the institutional investors who are the thought leaders in the life science investing marketplace.

Item 3. Legal Proceedings

Section 16(b) Action

On August 12, 2015, a Navidea shareholder filed an action in the United States District Court for the Southern District of New York against two funds managed by Platinum Management (NY) LLC (“Platinum”) alleging violations of Section 16(b) of the Securities Exchange Act of 1934, as amended, in connection with purchases and sales of the Company’s common stock by the Platinum funds, and seeking disgorgement of the short-swing profits realized by the funds (the “Litigation”). The Company was named as a nominal defendant in the Litigation.

The Litigation was resolved on the terms set forth in a settlement agreement (the “Settlement Agreement”). The Settlement Agreement was subject to a pending joint motion for approval. The Court approved the settlement on Friday, July 1, 2016. In accordance with the terms of the Settlement Agreement, the interest rate on the Platinum credit facility was reduced by 6% to 8.125% effective July 1, 2016. In addition, Platinum assumed the obligation to pay the legal costs associated with the Litigation.

Sinotau Litigation – NAV4694

On August 31, 2015, Sinotau filed a suit for damages, specific performance, and injunctive relief against the Company in the United States District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company’s NAV4694 product candidate and technology. The Company believed the suit was without merit and filed a motion to dismiss the action. In September 2016, the Court denied the motion to dismiss. The Company filed its answer to the complaint and the case is currently in the discovery phase. At this time it is not possible to determine with any degree of certainty the ultimate outcome of this legal proceeding, including making a determination of liability. The Company intends to vigorously defend the case.

In July 2016, the Company executed a term sheet with Cerveau Technologies, Inc. (“Cerveau”) as a designated party for the rights resulting from the relationship between Navidea and Sinotau. The term sheet outlined the terms of a potential agreement between the parties to sublicense NAV4694 to Cerveau in return for license fees, milestone payments and royalties. With the exception of certain provisions, the term sheet was non-binding and was subject to the agreement of AstraZeneca, from whom the Company has licensed the NAV4694 technology. The Company had 60 days to execute a definitive agreement, however no definitive agreement was reached. Discussions related to the potential licensure or divestiture of NAV4694 are ongoing.

CRG Litigation

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company’s primary bank accounts and took possession of \$4.1 million that was on deposit, applying \$3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining \$189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million (the “Deposit Amount”) of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents (the “Final Payoff Amount”). The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million (the “Low Payoff Amount”) and no more than \$66 million (the “High Payoff Amount”). In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7 million letter of credit in favor of CRG (at the Company’s cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414’s indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG’s letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414,

and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The Company and CRG also agreed that the \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case would be released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7 million letter of credit, and on March 7, 2017, CRG posted a \$12 million letter of credit, each as required by the Global Settlement Agreement. The Texas hearing is currently set for July 3, 2017.

Former CEO Arbitration

On May 12, 2016 the Company received a demand for arbitration through the American Arbitration Association, Columbus, Ohio, from Ricardo J. Gonzalez, the Company's then Chief Executive Officer, claiming that he was terminated without cause and, alternatively, that he resigned in accordance with Section 4G of his Employment Agreement pursuant to a notice received by the Company on May 9, 2016. On May 13, 2016, the Company notified Mr. Gonzalez that his failure to undertake responsibilities assigned to him by the Board of Directors and otherwise work after being ordered to do so on multiple occasions constituted an effective resignation, and the Company accepted that resignation. The Company rejected the resignation of Mr. Gonzalez pursuant to Section 4G of his Employment Agreement. Also, the Company notified Mr. Gonzalez that, alternatively, his failure to return to work after the expiration of the cure period provided in his Employment Agreement constituted cause for his termination under his Employment Agreement. Mr. Gonzalez is seeking severance and other amounts claimed to be owed to him under his Employment Agreement. In addition, the Company filed counterclaims against Mr. Gonzalez alleging malfeasance by Mr. Gonzalez in his role as Chief Executive Officer. Mr. Gonzalez has withdrawn his claim for additional severance pursuant to Section 4G of his Employment Agreement, and the Company has withdrawn its counterclaims. Mr. Gonzalez has made settlement demands but the Company has made no counteroffers to date. A three-person arbitration board has been chosen and a hearing is set for April 3-7, 2017 in Columbus, Ohio.

Former Director Litigation

On August 12, 2016, the Company commenced an action in the Superior Court of California for damages and injunctive relief against former Navidea Chairman and MT Board Member Anton Gueth. The Complaint alleges, in part, that Mr. Gueth intentionally failed to disclose his prior existing relationship with CRG, in addition to multiple breaches including duty, loyalty and contract, interference and misappropriation. The litigation was dismissed without prejudice on December 19, 2016.

FTI Consulting, Inc. Litigation

On October 11, 2016, FTI Consulting, Inc. ("FTI") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in excess of \$782,600 comprised of: (i) \$730,264 for investigative and consulting services FTI alleges to have provided to the Company pursuant to an Engagement Agreement, and (ii) in excess of \$52,337 for purported interest due on unpaid invoices, plus attorneys' fees, costs and expenses. On November 14, 2016, the Company filed an Answer and Counterclaim denying the allegations of the Complaint and seeking damages on its Counterclaim, in an amount to be determined at trial, for intentional overbilling by FTI. On February 7, 2017, a preliminary conference was held by the Court at which time a scheduling order governing discovery was issued. The Court set August 31, 2017 as the deadline for FTI to file a Note of Issue and Certificate of Readiness for trial. Discovery will commence within the next few weeks. The Company intends to vigorously defend the action.

Sinotau Litigation – Tc 99m Tilmanocept

On February 1, 2017, Navidea filed suit against Sinotau in the U.S. District Court for the Southern District of Ohio. The Company's complaint included claims seeking a declaration of the rights and obligations of the parties to an agreement regarding rights for the Tc 99m tilmanocept product in China and other claims. The complaint sought a temporary restraining order ("TRO") and preliminary injunction to prevent Sinotau from interfering with the Company's Asset Sale to Cardinal Health 414. On February 3, 2017, the Court granted the TRO and extended it until March 6, 2017. The Asset Sale closed on March 3, 2017. On March 6, the Court dissolved the TRO as moot. The Ohio case remains open because all issues raised in the complaint have not been resolved.

Sinotau also filed a suit against the Company and Cardinal Health 414 in the U.S. District Court for the District of Delaware on February 2, 2017. On February 18, 2017, the Company and Cardinal Health 414 moved to stay the case pending the outcome of the Ohio case. The Court granted the motion on March 1, 2017, and the stay remains in effect.

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.

	<u>High</u>	<u>Low</u>
<i>Fiscal Year 2016:</i>		
First Quarter	\$ 1.35	\$ 0.75
Second Quarter	1.51	0.51
Third Quarter	1.14	0.26
Fourth Quarter	1.16	0.57
<i>Fiscal Year 2015:</i>		
First Quarter	\$ 1.96	\$ 1.55
Second Quarter	1.67	1.22
Third Quarter	2.50	1.28
Fourth Quarter	2.40	1.32

As of March 1, 2017, we had approximately 600 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.

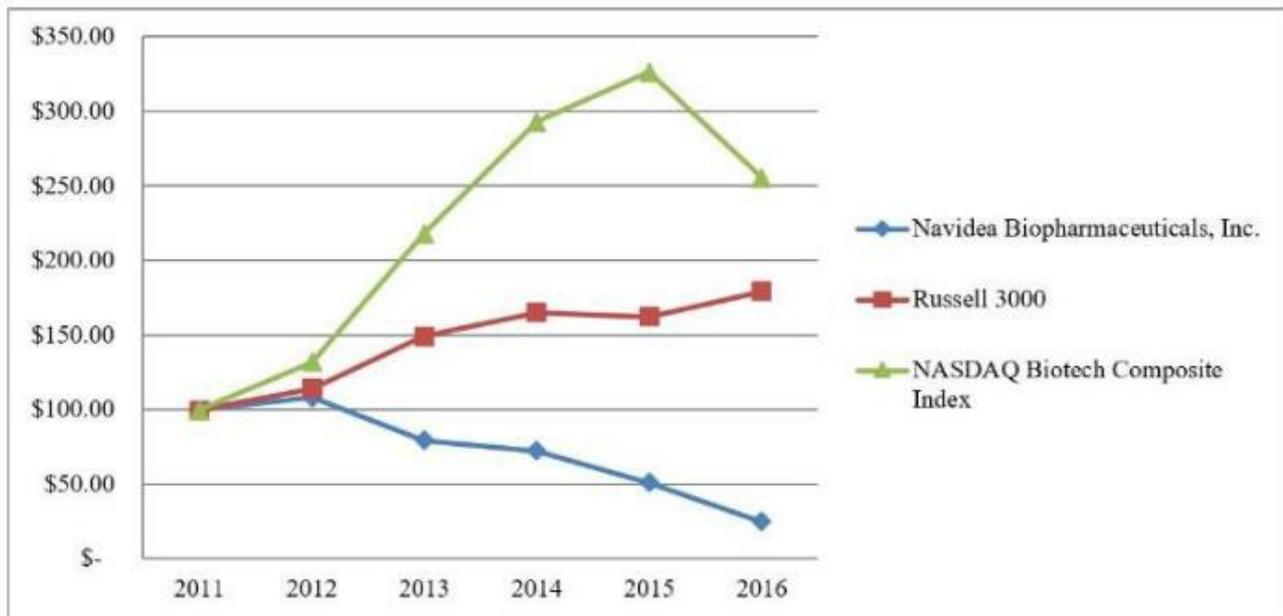
There were no repurchases of our common stock during the three-month period ended December 31, 2016.

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, 2011 through December 31, 2016. This graph assumes an investment in the Company's common stock and the indices of \$100 on December 31, 2011 and that any 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 12/31/2011 in stock or index, including reinvestment of dividends.

Cumulative Total Return as of December 31,

	2011	2012	2013	2014	2015	2016
Navidea Biopharmaceuticals	\$ 100.00	\$ 108.02	\$ 79.01	\$ 72.14	\$ 50.76	\$ 24.43
Russell 3000	100.00	113.98	149.25	164.85	162.42	179.34
NASDAQ Biotechnology	100.00	131.91	218.45	292.93	326.39	255.62

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 firms. 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 2015 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,				
	2016	2015	2014	2013	2012
Statement of Operations Data:					
Revenue	\$ 21,970	\$ 13,249	\$ 6,275	\$ 1,131	\$ 79
Cost of goods sold	2,297	1,755	1,586	333	—
Research and development expenses	8,883	12,788	16,780	23,710	16,890
Selling, general and administrative expenses	13,013	17,257	15,542	15,526	11,178
Loss from operations	<u>(2,223)</u>	<u>(18,551)</u>	<u>(27,633)</u>	<u>(38,438)</u>	<u>(27,989)</u>
Other expenses, net	<u>(12,086)</u>	<u>(10,208)</u>	<u>(8,094)</u>	<u>(4,261)</u>	<u>(1,168)</u>
Benefit from income taxes	—	436	—	—	—
Loss from continuing operations	(14,309)	(28,323)	(35,727)	(42,699)	(29,157)
Discontinued operations, net of tax effect	—	759	—	—	—
Net loss	(14,309)	(27,564)	(35,727)	(42,699)	(29,157)
Less loss attributable to noncontrolling interest	(1)	(1)	—	—	—
Deemed dividend	—	(46)	—	—	—
Preferred stock dividends	—	—	—	—	(43)
Loss attributable to common stockholders	<u>\$ (14,308)</u>	<u>\$ (27,609)</u>	<u>\$ (35,727)</u>	<u>\$ (42,699)</u>	<u>\$ (29,200)</u>
(Loss) income per common share (basic and diluted):					
Continuing operations	\$ (0.09)	\$ (0.19)	\$ (0.24)	\$ (0.35)	\$ (0.29)
Discontinued operations	\$ —	\$ 0.01	\$ —	\$ —	\$ —
Loss attributable to common stockholders	\$ (0.09)	\$ (0.18)	\$ (0.24)	\$ (0.35)	\$ (0.29)
Shares used in computing (loss) income per common share: ⁽¹⁾					
Basic and diluted	155,422	151,180	148,748	121,809	99,060

	As of December 31,				
	2016	2015	2014	2013	2012
Balance Sheet Data:					
Total assets	\$ 12,462	\$ 14,965	\$ 11,830	\$ 39,626	\$ 11,677
Long-term liabilities	10,266	62,616	32,573	32,703	7,107
Accumulated deficit	(394,855)	(380,547)	(352,984)	(317,257)	(274,558)

⁽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, convertible debt, 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. is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on our Manocept platform to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care.

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc 99m tilmanocept, the first product developed by Navidea based on the platform.

On March 3, 2017, the Company completed the Asset Sale to Cardinal Health 414, as discussed previously under "Development of the Business." Pursuant to the Purchase Agreement, we sold all of our assets used, held for use, or intended to be used in operating the Business, including Lymphoseek, in Canada, Mexico and the United States. Upon closing of the Asset Sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect.

The Asset Sale to Cardinal Health 414 significantly improved our financial condition and our ability to continue as a going concern. The Company also continues working to establish new sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be supported by our revenues.

Other than Tc 99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, none of the Company's drug product candidates have been approved for sale in any market.

Executive Summary

Our primary development efforts over the last few years have been focused on diagnostic products including Tc 99m tilmanocept, as well as other diagnostic and therapeutic line extensions based on our Manocept platform.

Building on the success of Tc 99m tilmanocept, the flexible and versatile Manocept platform acts as an engine for the design of purpose-built molecules offering the potential to be utilized across a range of diagnostic modalities, SPECT, PET, intra-operative and/or optical-fluorescence detection in a variety of disease states.

We have advanced three additional imaging product candidates into clinical testing.

Cardiovascular Disease – We have completed a nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc 99m tilmanocept product dosed subcutaneously. The results of this study were recently published in the *Journal of Infectious Diseases*, confirming that the Tc 99m tilmanocept product can both quantitatively as well as qualitatively target non-calcified plaque in the aortic arch (NIH/NHLBI Grant 1 R43 HL127846-01). We have applied for follow-on NIH/NHLBI support to fund additional clinical studies. These studies are currently under development and design for both Phase 1 and Phase 2 trials.

Rheumatoid Arthritis – We have initiated two dosing studies in RA. The first study, now complete, included 18 subjects (12 with active disease and 6 controls) who were dosed subcutaneously. In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have initiated and partially completed a study dosing the Tc 99m tilmanocept product IV. These studies have been supported through a SBIR grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1).

Kaposi's Sarcoma – Although we initiated and completed a study of KS in 2015, we received additional funding from the NIH in 2016 to continue studies in this disease. The new support not only continues the imaging of cutaneous elements of this disease but expands this to imaging of visceral disease via IV administration of Tc99m tilmanocept (NIH/NCI 1 R44 CA192859-01A1). Additionally, we received funding to support the therapeutic initiative for KS employing a select form of the class 1000 agent under current evaluation. The Company has already completed a portion of the Phase 1 SBIR portion of this award (1 R44 CA206788-01).

Based on performance in these very large imaging market opportunities the Company anticipates continued investment in these programs including initiating studies designed to obtain new approvals for the Tc 99m tilmanocept product.

Preclinical data generated by the Company in studies using tilmanocept linked to a therapeutic agent also suggest that tilmanocept's binding affinity to CD206 receptors demonstrates the potential for this technology to be useful in treating diseases linked to the over-activation of macrophages. This includes various cancers as well as autoimmune, infectious, CV, and CNS diseases. Our efforts in this area were further supported by the 2015 formation of MT, a majority-owned subsidiary that was formed specifically to explore therapeutic applications for the Manocept platform.

MT has been set up to pursue the drug delivery model. This model enables the Company to leverage its technology over many potential therapeutic applications and with multiple partners simultaneously without significant capital outlays. To date, the Company has developed two lead families of therapeutic products. The MT1000 class is designed to deplete activated macrophages via apoptosis. The MT2000 class is designed to modulate activated macrophages from a classically activated phenotype to the alternatively activated phenotype. Both families have been tested in a number of disease models in rodents. Navidea has sublicensed all of its intellectual property related to potential therapeutic applications of tilmanocept to its MT subsidiary.

We continue to seek to partner or out-license NAV4694. The NAV5001 sublicense was terminated in April 2015.

In the near term, the Company intends to continue to advance our additional imaging product candidates into advanced clinical testing with the goal of extending the regulatory approvals for use of the Tc 99m tilmanocept product. 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, and potential options for advancing development.

Our Outlook

Our operating expenses in recent years have been focused primarily on support of Tc 99m tilmanocept, our Manocept platform, and NAV4694 and NAV5001 product development. We incurred approximately \$8.9 million, \$12.8 million and \$16.8 million in total on research and development activities during the years ended December 31, 2016, 2015 and 2014, respectively. Of the total amounts we spent on research and development during those periods, 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 *	2016	2015	2014
Tc 99m tilmanocept	\$ 2,002,449	\$ 2,365,128	\$ 995,511
Manocept platform	1,045,102	767,431	503,587
Macrophage Therapeutics	679,961	538,813	—
NAV4694	1,590,607	3,448,724	6,788,286
NAV5001	97,602	385,344	1,441,442

* Certain development program expenditures were offset by grant reimbursement revenues totaling \$2.8 million, \$1.7 million, and \$1.7 million during the years ended December 31, 2016, 2015 and 2014, respectively.

We expect to continue the advancement of our efforts with our Manocept platform during 2017. The divestiture of NAV5001 and the suspension of active patient accrual in our NAV4694 trials have decreased our development costs over the past year, however, we continue to incur costs to maintain the trials and drug production while we complete our partnering/divestiture activities. We expect our total research and development expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be lower in 2017 than in 2016. This estimate excludes charges related to our subsidiary, Macrophage Therapeutics, Inc., which are currently expected to be funded separately.

Tc 99m tilmanocept is approved by the EMA for use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity in the EU. There can be no assurance that Tc 99m tilmanocept will achieve regulatory approval in any other market outside the EU, or if approved in those markets, that it will achieve market acceptance in the EU or any other market. See Risk Factors.

In March 2017, Navidea completed the Asset Sale to Cardinal Health 414, as discussed previously under “Development of the Business.” In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately \$80.6 million after adjustments based on inventory being transferred and an advance of \$3 million of guaranteed earnout payments as part of the CRG settlement (as described in Item 3 – Legal Proceedings), (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414’s right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG (as described in Item 3 – Legal Proceedings). Post-closing and after paying off our outstanding indebtedness and transaction-related expenses, Navidea has approximately \$15.6 million in cash and \$3.7 million in payables, a large portion of which is tied to the 4694 program which Navidea is seeking to divest in the near term. Thus, the completion of the Asset Sale significantly improved our financial condition and our ability to continue as a going concern.

Our marketing partners have historically shared a portion of the direct marketing, sales and distribution costs related to the sale of Tc 99m tilmanocept. We anticipate that we will incur costs related to supporting the other product, regulatory, manufacturing and commercial activities related to the potential marketing registration and sale of Tc 99m tilmanocept in the EU and other markets.

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, RA, vulnerable plaque/atherosclerosis, TB and other disease states, to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform. 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, and potential options for advancing development. There can be no assurance 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.

Results of Operations

Years Ended December 31, 2016 and 2015

Net Sales and Margins. Net sales of Lymphoseek were \$17.0 million during 2016, compared to \$10.3 million during 2015. Net sales of Lymphoseek during 2016 included \$500,000 related to reaching a sales milestone under the Cardinal Health 414 distribution agreement, and reflected continued efforts to increase sales through increased adoption of Lymphoseek. Gross margins on net sales of Lymphoseek were 87% and 83% for 2016 and 2015, respectively. Cost of goods sold in 2015 included a net benefit of \$253,000 related to our ability to sell certain previously reserved inventory, partially offset by net inventory losses of \$93,000 related to a production matter and reserves for inventory obsolescence totaling \$52,000 related to specific lots which expired during the period. Cost of goods sold in both periods included post-production testing activities required by regulatory authorities, which are charged as period costs, and a royalty on net sales payable under our license agreement with UCSD.

Lymphoseek License Revenue. During 2016 and 2015, we recognized \$1.2 million and \$833,000, respectively, of the \$2.0 million non-refundable upfront payment received by the Company related to the Lymphoseek license and distribution agreement for Europe. The Company had been recognizing this revenue on a straight-line basis over two years, however the remaining deferred revenue of \$417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, five months earlier than originally anticipated. During 2016, we also recognized \$500,000 of milestone revenue upon obtaining European approval of the reduced-mass vial, as well as \$127,000 reimbursement of certain clinical development costs, in accordance with the terms of the Lymphoseek distribution agreement for Europe. During 2015, we recognized \$300,000 of Lymphoseek license revenue from a non-refundable milestone payment received by the Company related to the Lymphoseek distribution agreement for China, for which the Company has no future obligations.

Grant and Other Revenue. During 2016, we recognized \$3.1 million of grant and other revenue as compared to \$1.9 million in 2015. Grant revenue during 2016 was primarily related to SBIR grants from the NIH supporting Manocept, Lymphoseek, NAV4694 and therapeutic development. Grant revenue during 2015 was primarily related to SBIR grants from the NIH supporting NAV4694, Lymphoseek and Manocept development. Grant and other revenue during 2016 included \$173,000 from sales of non-commercial product to our European distribution partner. Grant and other revenue for 2016 and 2015 also included \$33,000 and \$140,000, respectively, related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased \$3.9 million, or 31%, to \$8.9 million during 2016 from \$12.8 million during 2015. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of \$1.9 million including decreased clinical trial costs and manufacturing-related activities offset by increased licensing costs, while we continued our efforts to divest the program; (ii) decreased Lymphoseek development costs of \$363,000 including decreased manufacturing-related activities and pre-clinical testing, offset by increased licensing, clinical trial and regulatory costs; and (iii) decreased NAV5001 development costs of \$288,000 including decreased manufacturing-related activities and clinical trial costs; offset by (iv) increased Manocept platform development costs of \$278,000 including increased clinical trial costs offset by decreased preclinical testing, license fees and manufacturing-related activities; and (v) increased therapeutics development costs of \$141,000 including increased consulting costs offset by decreased scientific advisory board fees and manufacturing-related activities. The net decrease in research and development expenses also included decreased compensation including incentive-based awards and other expenses related to net decreased headcount of \$1.7 million following the first quarter 2015 reduction in force.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased \$4.3 million, or 25%, to \$13.0 million during 2016 from \$17.3 million during 2015. The net decrease was primarily due to decreased general and administrative headcount of \$2.4 million following the first quarter 2015 reduction in force coupled with decreased travel, office and other support costs of \$689,000, contracted medical science liaisons of \$670,000, business development consulting services of \$668,000, market development expenses related to Lymphoseek of \$610,000, and investor relations of \$212,000, offset by increased legal and professional services of \$730,000 coupled with increased commercial and medical headcount of \$317,000.

Other Income (Expense). Other expense, net, was \$12.1 million during 2016 as compared to other expense, net of \$10.2 million during 2015. Interest expense, net increased \$8.0 million to \$14.9 million during 2016 from \$6.9 million for 2015, primarily due to the higher outstanding balances and higher interest rates related to the CRG Term Loan in 2016 versus the Oxford Notes in 2015, coupled with the higher outstanding balances of the Platinum Note in 2016 versus 2015. Of this interest expense, \$2.0 million and \$493,000 in 2016 and 2015, respectively, was non-cash in nature related to the amortization of debt issuance costs and debt discounts related to the CRG Term Loan and Oxford Notes. An additional \$1.6 million and \$2.0 million of this interest expense was compounded and added to the balance of our notes payable during 2016 and 2015, respectively. CRG collection fees of \$778,000, a prepayment premium of \$2.1 million, and the remaining unamortized balance of the CRG debt discount of \$2.0 million, as previously disclosed, were also recorded as interest expense during 2016. For 2016 and 2015, we recorded non-cash income (expense) of \$2.9 million and (\$615,000), respectively, related to changes in the estimated fair value of financial instruments. During 2016 and 2015, we recorded non-cash equity in the loss of R-NAV of \$15,000 and \$305,000, respectively. During 2016, we also recorded a non-cash loss on the disposal of our investment in R-NAV of \$40,000. During 2015, we recorded \$2.4 million of losses on the extinguishment of the Oxford Notes.

Income from Discontinued Operations. In connection with the sale of our GDS Business to Devicor in August 2011, Devicor 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 through 2017. During 2015, we recorded net income from the GDS Business of \$759,000 related to royalty amounts earned based on 2015 GDS Business revenue. The royalty amount of \$1.2 million was offset by \$436,000 in estimated taxes which were allocated to discontinued operations, but were fully offset by the tax benefit from our net operating loss for 2015. We did not record any income from discontinued operations in 2016.

Years Ended December 31, 2015 and 2014

Net Sales and Margins. Net sales of Lymphoseek were \$10.3 million during 2015, compared to \$4.2 million during 2014. The increase was primarily the result of continued efforts to increase sales. Gross margins on net sales of Lymphoseek were 83% and 63% for 2015 and 2014, respectively. Cost of goods sold in 2015 included a net benefit of \$253,000 related to our ability to sell certain previously reserved inventory, partially offset by net inventory losses of \$93,000 related to a production matter and reserves for inventory obsolescence totaling \$52,000 related to specific lots which expired during the period. Cost of goods sold in 2014 included a reserve for inventory obsolescence of \$539,000 related to a specific lot which was originally produced for validation purposes but was nearing its product expiry and therefore was no longer expected to be sold. Cost of goods sold in both periods included post-production testing activities required by regulatory authorities, which are charged as one-time period costs, and a royalty on net sales payable under our license agreement with UCSD.

Lymphoseek License Revenue. During 2015, we recognized \$833,000 of the \$2.0 million non-refundable upfront payment received by the Company related to the Lymphoseek license and distribution agreement for Europe, which the Company was recognizing on a straight-line basis over two years. During 2015 and 2014, we recognized \$300,000 of Lymphoseek license revenue from non-refundable milestone payments received by the Company related to the Lymphoseek distribution agreement for China, for which the Company has no future obligations.

Grant and Other Revenue. During 2015, we recognized \$1.9 million of grant and other revenue as compared to \$1.7 million in 2014. Grant revenue during 2015 was primarily related to SBIR grants from the NIH supporting NAV4694, Lymphoseek and Manocept platform development. Grant revenue during 2014 was primarily related to SBIR grants from the NIH supporting NAV4694 and NAV1800 development. Grant and other revenue for 2015 and 2014 also included \$140,000 and \$90,000, respectively, related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased \$4.0 million, or 24%, to \$12.8 million during 2015 from \$16.8 million during 2014. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of \$3.3 million including decreased clinical trial costs and manufacturing-related activities while we continued our efforts to divest the program; and (ii) decreased NAV5001 development costs of \$1.1 million including decreased clinical trial costs and manufacturing-related activities; offset by (iii) increased Lymphoseek development costs of \$1.4 million due to a refund of supplemental NDA filing fees of \$1.1 million reducing costs incurred in 2014, increased manufacturing-related activities, preclinical testing, and clinical trial costs, offset by decreased license fees; (iv) increased therapeutics development costs of \$539,000 including increased scientific advisory board fees and manufacturing-related activities; and (v) increased Manocept platform development costs of \$264,000 including increased clinical trial costs, license fees and manufacturing-related activities, offset by decreased preclinical testing. The net decrease in research and development expenses also included decreased compensation including incentive-based awards and other expenses related to net decreased headcount of \$1.0 million following the first quarter 2015 and second quarter 2014 reductions in force coupled with decreased travel, office and other support costs of \$767,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$1.8 million, or 11%, to \$17.3 million during 2015 from \$15.5 million during 2014. The net increase was primarily due to increased compensation including incentive-based awards and other expenses related to increased internal commercial and medical education headcount coupled with costs related to the first quarter 2015 reduction in force (discussed in Note 16 to the consolidated financial statements). The net increase in selling, general and administrative expenses also included increased legal and professional services, license fees related to Lymphoseek, investor relations costs, market development expenses related to NAV4694, and travel, office and other support costs, offset by decreased costs for contracted medical science liaisons and decreased professional services and market development expenses related to Lymphoseek.

Other Income (Expense). Other expense, net, was \$10.2 million during 2015 as compared to other expense, net of \$8.1 million during 2014. Interest expense, net increased \$3.2 million to \$6.9 million during 2015 from \$3.7 million for 2014, primarily due to the higher outstanding balances and higher interest rates related to the CRG Term Loan and Oxford Notes in 2015 versus the Oxford Notes and GECC/MidCap Notes in 2014, coupled with the higher outstanding balances and higher interest rates of the Platinum Note in 2015 compared to 2014. Of this interest expense, \$493,000 and \$844,000 in 2015 and 2014, respectively, was non-cash in nature related to the amortization of debt discounts related to the CRG Term Loan, Oxford Notes and GECC/MidCap Notes. An additional \$2.0 million of this interest expense was compounded and added to the balance of our notes payable during 2015. During 2015 and 2014, we recorded \$2.4 million and \$2.6 million, respectively, of losses on the extinguishment of the Oxford Notes and GECC/MidCap Notes. For 2015 and 2014, we recorded non-cash expenses of \$615,000 and \$1.3 million, respectively, related to changes in the estimated fair value of financial instruments. During 2015 and 2014, we recorded non-cash equity in the loss of R-NAV of \$305,000 and \$524,000, respectively.

Income from Discontinued Operations. In connection with the sale of our GDS Business to Devicor in August 2011, Devicor 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 through 2017. During 2015, we recorded net income from the GDS Business of \$759,000 related to royalty amounts earned based on 2015 GDS Business revenue. The royalty amount of \$1.2 million was offset by \$436,000 in estimated taxes which were allocated to discontinued operations, but were fully offset by the tax benefit from our net operating loss for 2015. We did not record any income from discontinued operations in 2014.

Liquidity and Capital Resources

Cash balances decreased to \$1.5 million at December 31, 2016 from \$7.2 million at December 31, 2015. The net decrease was primarily due to \$4.1 million cash withdrawn by CRG for collection fees, prepayment premium and a backend facility fee, and \$5.0 million restricted cash in a pledged collateral account over which CRG had control and a court escrow account, offset by \$3.6 million provided by operations.

All of our material assets, except our intellectual property, had been pledged as collateral for our borrowings under the CRG Loan Agreement. In addition to the security interest in our assets, the CRG Loan Agreement carried covenants that imposed significant requirements on us, including, among others, requirements that we (1) pay all principal, interest and other charges on the outstanding balance of the borrowed funds when due; (2) maintain liquidity of at least \$5 million during the term of the CRG Loan Agreement; and (3) meet certain annual EBITDA or revenue targets (\$22.5 million of Te 99m tilmanocept sales revenue in 2016) as defined in the CRG Loan Agreement. The events of default under the CRG Loan Agreement also included a failure of Platinum to perform its funding obligations under the Platinum Loan Agreement at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum's repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. An event of default would entitle CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

As previously described in Item 3 – Legal Proceedings, on March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Texas hearing is currently set for July 3, 2017.

In addition, the Platinum Loan Agreement carries standard non-financial covenants typical for commercial loan agreements 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.

The Platinum Loan Agreement includes a covenant that results in an event of default on the Platinum Loan Agreement upon default on the CRG Loan Agreement. As discussed above, the Company is maintaining its position that CRG's alleged claims do not constitute events of default under the CRG Loan Agreement and believes it has defenses against such claims. The Company has obtained a waiver from Platinum confirming that we are not in default under the Platinum Loan Agreement as a result of the alleged default on the CRG Loan Agreement and as such, we are currently in compliance with all covenants under the Platinum Loan Agreement.

As of December 31, 2016, the outstanding principal balance of the Platinum Note was approximately \$9.5 million, with \$27.3 million currently available under the credit facility. An additional \$15 million was potentially available under the credit facility on terms to be negotiated. However, based on Platinum's recent filing for Chapter 15 bankruptcy protection, Navidea has substantial doubt about Platinum's ability to fund future draw requests under the credit facility.

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to PPCO an aggregate of approximately \$7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

Operating Activities. Cash from operations increased \$22.7 million to \$3.6 million provided during 2016 compared to \$19.1 million used in 2015.

Accounts and other receivables decreased to \$1.8 million at December 31, 2016 from \$3.7 million at December 31, 2015, primarily due to the receipt of \$1.2 million of royalties from Devicor associated with the 2011 sale of the GDS Business coupled with decreased receivables due from Cardinal Health 414 resulting from the advances received from Cardinal Health 414 during the fourth quarter of 2016, offset by increased amounts due from our European distribution partner related to the sale of non-commercial product.

Inventory levels increased to \$1.5 million at December 31, 2016 from \$653,000 at December 31, 2015, primarily due to finished goods, work in process and materials inventory produced offset by materials used in production and finished goods inventory sold. We expect inventory levels to decrease during 2017 following the Asset Sale to Cardinal Health 414.

Prepaid expenses and other current assets decreased slightly to \$1.0 million at December 31, 2016 from \$1.1 million at December 31, 2015, primarily due to increased legal retainers related to the CRG litigation, prepaid insurance and FDA annual fees, offset by amortization of the prior year's prepaid insurance and FDA annual fees.

Accounts payable increased to \$7.1 million at December 31, 2016 from \$1.8 million at December 31, 2015, primarily due to net increased payables due to legal and professional services, inventory, NAV4694, investor relations, Tc 99m tilmanocept, and therapeutics vendors. Of the increased accounts payable, at least \$894,000 is being disputed by the Company's current management. Accrued liabilities and other current liabilities increased to \$8.5 million at December 31, 2016 from \$3.0 million at December 31, 2015, primarily due to increased accruals for interest on the CRG debt and therapeutics development costs, offset by decreased accruals for NAV4694 development costs. Our payable and accrual balances are expected to decrease during 2017 following the Asset Sale to Cardinal Health 414 including ending our support of Tc 99m tilmanocept commercialization efforts in the U.S. and payoff of accrued interest associated with the CRG debt, coupled with continuing to decrease our support of NAV4694 development.

Deferred revenue increased to \$2.3 million at December 31, 2016 from \$1.2 million at December 31, 2015, primarily due to advances from Cardinal Health 414 against the proceeds from the Asset Sale of \$2.3 million, offset by recognition of \$1.2 million of the \$2.0 million non-refundable upfront payment received by the Company related to the Tc 99m tilmanocept license and distribution agreement for Europe. The Company had been recognizing this revenue on a straight-line basis over two years, however the remaining deferred revenue of \$417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, five months earlier than originally anticipated. Deferred revenue is expected to decrease during 2017 following the Asset Sale to Cardinal Health 414.

Investing Activities. Investing activities used \$39,000 during 2016 compared to using \$28,000 in 2015. Capital expenditures of \$39,000 during 2015 were primarily for Tc 99m tilmanocept production equipment and computers. Net payments related to the disposal of our investment in R-NAV of \$82,000 and capital expenditures of \$2,000, primarily for computer equipment, were offset by proceeds from sales of capital equipment of \$45,000 during 2016. Proceeds from sales of equipment of \$38,000 were offset by patent and trademark costs of \$27,000 during 2015. We expect our overall capital expenditures for 2017 will be slightly higher than for 2016 as we maintain our technology infrastructure.

Financing Activities. Financing activities used \$9.1 million during 2016 compared to providing \$20.8 million in 2015. The \$9.1 million used by financing activities in 2016 consisted primarily of restrictions placed on cash in an account controlled by CRG of \$5.0 million, payment of debt-related costs of \$3.9 million, and principal payments on notes payable of \$231,000, primarily related to the CRG debt. The \$20.8 million provided by financing activities in 2015 consisted primarily of proceeds from the CRG Term Loan of \$50.0 million, draws under the Platinum credit facility of \$4.5 million, and proceeds from issuance of MT Preferred Stock of \$500,000, offset by principal payments on the Oxford Notes of \$30.0 million, payment of debt-related costs of \$3.9 million, and a principal payment on the R-NAV note of \$333,000.

Investment in Macrophage Therapeutics, Inc.

In March 2015, MT, our previously wholly-owned subsidiary, entered into a Securities Purchase Agreement to sell up to 50 shares of its Series A Convertible Preferred Stock (“MT Preferred Stock”) and warrants to purchase up to 1,500 common shares of MT (MT Common Stock) to Platinum and Dr. Michael Goldberg (collectively, the “MT Investors”) for a purchase price of \$50,000 per unit. A unit consists of one share of MT Preferred Stock and 30 warrants to purchase MT Common Stock. Under the agreement, 40% of the MT Preferred Stock and warrants are committed to be purchased by Dr. Goldberg, and the balance by Platinum. The full 50 shares of MT Preferred Stock and warrants that may be sold under the agreement are convertible into, and exercisable for, MT Common Stock representing an aggregate 1% interest on a fully converted and exercised basis. Navidea owns the remainder of the MT Common Stock. On March 11, 2015, definitive agreements with the MT Investors were signed for the sale of the first tranche of 10 shares of MT Preferred Stock and warrants to purchase 300 shares of MT Common Stock to the MT Investors, with gross proceeds to MT of \$500,000.

In addition, we entered into a Securities Exchange Agreement with the MT Investors providing them an option to exchange their MT Preferred Stock for our common stock in the event that MT has not completed a public offering with gross proceeds to MT of at least \$50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing \$50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our common stock on the second anniversary of the initial closing or (ii) \$3.00. To the extent that the MT Investors do not timely exercise their exchange right, MT has the right to redeem their MT Preferred Stock for a price equal to \$58,320 per share. We also granted MT an exclusive license for certain therapeutic applications of the Manocept technology.

In December 2015 and May 2016, Platinum contributed an additional \$200,000 to MT. MT was not obligated to provide anything in return, although it was considered likely that the MT Board would ultimately authorize some form of compensation to Platinum. During the year ended December 31, 2016, the Company recorded the entire \$200,000 as a current liability pending determination of the form of compensation.

In July 2016, MT’s Board of Directors authorized modification of the original investments of \$300,000 by Platinum and \$200,000 by Dr. Goldberg to a convertible preferred stock with a 10% PIK coupon retroactive to the time the initial investments were made. The conversion price of the preferred will remain at the \$500 million initial market cap but a full ratchet will be added to enable the adjustment of conversion price, warrant number and exercise price based on the valuation of the first institutional investment round. In addition, the MT Board authorized issuance of additional convertible preferred stock with the same terms to Platinum as compensation for the additional \$200,000 of investments made in December 2015 and May 2016. As of the date of filing of this Form 10-K, final documents related to the above transactions authorized by the MT Board have not been completed.

Investment in R-NAV, LLC

In July 2014, Navidea formed a joint enterprise with Essex Woodlands-backed Rheumco, LLC, to develop and commercialize radiolabeled diagnostic and therapeutic products for rheumatologic and arthritic diseases. The joint enterprise, called R-NAV, LLC, combined Navidea’s proprietary Manocept CD206 macrophage targeting platform and Rheumco’s proprietary Tin-117m radioisotope technology to focus on leveraging the platforms across several indications with high unmet medical need, including the detection and treatment of RA and veterinary osteoarthritis.

Both Rheumco and Navidea contributed licenses for intellectual property and technology to R-NAV in exchange for common units in R-NAV. R-NAV was initially capitalized through a \$4.0 million investment from third-party private investors, and the technology contributions from Rheumco and Navidea. Navidea committed an additional \$1.0 million investment to be paid over three years, with \$333,334 in cash contributed at inception and a promissory note in the principal amount of \$666,666, payable in two equal installments on the first and second anniversaries of the transaction. In exchange for its capital and in-kind investment, the Company received 1,000,000 Series A preferred units of R-NAV (“Series A Units”) and 3,500,000 Common Units. The Company was to receive an additional 500,000 Series A Units for management and technical services associated with the programs described above to be performed by the Company for R-NAV pursuant to a services agreement. The Series A Units were convertible into Common Units at the option of the holder for a conversion price of \$1 per unit, subject to broad-based weighted average anti-dilution rights. Navidea initially owned approximately 33.7% of the combined entity.

Joint oversight over certain aspects of R-NAV was shared between Navidea and the other investors; Navidea did not control the operations of R-NAV. Navidea had three-year call options to acquire, at its sole discretion, all of the equity of R-NAV's TcRA Imaging, Inc. subsidiary ("TcRA") for \$10.5 million prior to the launch of a Phase 3 clinical trial for its development program, and all of the equity of R-NAV's SnRA Theragnostics, Inc. subsidiary at fair value upon completion of radiochemistry and biodistribution studies for its development program.

Navidea's investment in R-NAV was accounted for using the equity method of accounting. Navidea's equity in the loss of R-NAV was \$15,000 for the year ended December 31, 2016.

Effective May 31, 2016, Navidea terminated its joint venture with R-NAV. Under the terms of the agreement, Navidea (1) transferred all of its shares of R-NAV, consisting of 1,500,000 Series A Units and 3,500,000 Common Units, to R-NAV; and (2) paid \$110,000 in cash to R-NAV. In exchange, R-NAV (1) transferred all of its shares of TcRA to Navidea, thereby returning the technology licensed to TcRA to Navidea; and (2) forgave the \$333,333 remaining on the promissory note. The Company's obligation to provide \$500,000 of in-kind services to R-NAV was being recognized as those services were provided. The Company provided \$15,000 of in-kind services during the five-month period ended May 31, 2016. As of the date of termination, the Company had \$383,000 of in-kind services remaining to provide under this obligation. This obligation ceased on May 31, 2016 under the terms of the agreement. Neither Navidea nor R-NAV has any further obligations of any kind to either party.

Platinum Credit Facility

The Platinum Loan Agreement, as amended, provides us with a credit facility of up to \$50 million. We drew a total of \$4.5 million under the credit facility during the year ended December 31, 2015. We did not make any draws under the credit facility during the years ended December 31, 2016 and 2014. The credit facility bears interest at 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 CRG Term Loan plus 0.125%, compounded monthly. In accordance with the terms of a Section 16(b) Settlement Agreement, Platinum agreed to forgive interest owed on the credit facility in an amount equal to 6%, effective July 1, 2016. As of December 31, 2016, the effective interest rate was 8.125%. \$1.0 million and \$761,000 of interest was compounded and added to the balance of the Platinum Note during the years ended December 31, 2016 and 2015, respectively. Platinum has the right, at Platinum's option subject to certain conditions, to convert all principal and interest outstanding under the Platinum Loan Agreement (the Conversion Amount), but not until such time as the average daily volume weighted average price of the Company's common stock for the ten preceding trading days exceeds \$2.53 per share. The number of shares of Navidea's common stock to be issued upon such conversion is 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 Loan Agreement matures six months following the maturity or earlier repayment of the CRG Term Loan.

The Platinum Loan Agreement carries standard non-financial covenants typical for commercial loan agreements 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.

The Platinum Loan Agreement includes a covenant that results in an event of default on the Platinum Loan Agreement upon default on the CRG Loan Agreement. As discussed below, the Company is maintaining its position that CRG's alleged claims do not constitute events of default under the CRG Loan Agreement and believes it has defenses against such claims. The Company has obtained a waiver from Platinum confirming that we are not in default under the Platinum Loan Agreement as a result of the alleged default on the CRG Loan Agreement and as such, we are currently in compliance with all covenants under the Platinum Loan Agreement.

As of December 31, 2016, the remaining outstanding principal balance of the Platinum Note was approximately \$9.5 million, consisting of \$7.7 million of draws and \$1.8 million of compounded interest, with \$27.3 million still available under the credit facility. An additional \$15 million was potentially available under the credit facility on terms to be negotiated. However, based on Platinum's recent filing for Chapter 15 bankruptcy protection, Navidea has substantial doubt about Platinum's ability to fund future draw requests under the credit facility.

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to PPCO an aggregate of approximately \$7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

Capital Royalty Partners II, L.P. Debt

In May 2015, Navidea and MT, as guarantor, executed a Term Loan Agreement with CRG in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of \$50 million, with an additional \$10 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. Closing and funding of the CRG Term Loan occurred on May 15, 2015 (the "Effective Date"). The principal balance of the CRG Term Loan bore interest from the Effective Date at a per annum rate of interest equal to 14.0%. Through March 31, 2019, the Company had the option of paying (i) 10.00% of the per annum interest in cash and (ii) 4.00% of the per annum interest as compounded interest which is added to the aggregate principal amount of the CRG Term Loan. During 2016 and 2015, \$553,000 and \$1.3 million of interest was compounded and added to the balance of the CRG Term Loan. In addition, the Company began paying the cash portion of the interest in arrears on June 30, 2015. Principal was due in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, was due and payable in full on March 31, 2021.

Pursuant to a notice of default letter sent to Navidea by CRG, the Company stopped compounding interest in the second quarter of 2016 and began recording accrued interest. As of December 31, 2016, \$5.8 million of accrued interest is included in accrued liabilities and other on the consolidated balance sheets. As of December 31, 2016, the outstanding principal balance of the CRG Term Loan was \$51.7 million.

The CRG Term Loan was collateralized by a security interest in substantially all of the Company's assets. In addition, the CRG Loan Agreement required that the Company adhere to certain affirmative and negative covenants, including 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 CRG Loan Agreement. The Lenders were entitled to accelerate the payment terms of the CRG Loan Agreement upon the occurrence of certain events of default set forth therein, which included the failure of the Company to make timely payments of amounts due under the CRG Loan Agreement, the failure of the Company to adhere to the covenants set forth in the CRG Loan Agreement, and the insolvency of the Company. The covenants of the CRG Loan Agreement included a covenant that the Company shall have EBITDA of no less than \$5 million in each calendar year during the term or revenues from sales of Tc 99m tilmanocept in each calendar year during the term of at least \$22.5 million in 2016, with the target minimum revenue increasing in each year thereafter until reaching \$45 million in 2020. However, if the Company were to fail to meet the applicable minimum EBITDA or revenue target in any calendar year, the CRG Loan Agreement provided the Company a cure right if it raises 2.5 times the EBITDA or revenue shortfall in equity or subordinated debt and deposits such funds in a separate blocked account. Additionally, the Company was required to maintain liquidity, defined as the balance of unencumbered cash and permitted cash equivalent investments, of at least \$5 million during the term of the CRG Term Loan. The events of default under the CRG Loan Agreement also included a failure of Platinum to perform its funding obligations under the Platinum Loan Agreement at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum's repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. An event of default would entitle CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of \$4.1 million that was on deposit, applying \$3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining \$189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million (the "Deposit Amount") of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents (the "Final Payoff Amount"). The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million (the "Low Payoff Amount") and no more than \$66 million (the "High Payoff Amount"). In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earned payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The Company and CRG also agreed that the \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case would be released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7 million letter of credit, and on March 7, 2017, CRG posted a \$12 million letter of credit, each as required by the Global Settlement Agreement. The Texas hearing is currently set for July 3, 2017.

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 million, 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 began making monthly payments of interest only on April 1, 2014, and monthly payments of principal and interest beginning April 1, 2015. In May 2015, in connection with the consummation of the CRG Loan Agreement, the Company repaid all amounts outstanding under the Oxford Loan Agreement. The payoff amount of \$31.7 million included payments of \$289,000 as a pre-payment fee and \$2.4 million as an end-of-term final payment fee. The Series KK warrants remained outstanding as of December 31, 2016.

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”), pursuant to which we issued GECC and MidCap: (1) Term Notes in the aggregate principal amount of \$25,000,000 (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”). In March 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 \$26.7 million, including \$500,000 as a pre-payment fee and \$1,000,000 as an end-of-term final payment fee. The Series HH warrants remained outstanding as of December 31, 2016.

Cardinal Health 414 Asset Sale

On March 3, 2017, pursuant to a Purchase Agreement dated November 23, 2016, the Company completed its previously announced sale to Cardinal Health 414 of its assets used, held for use, or intended to be used in operating the Business, including the Product, in the Territory (giving effect to the License-Back and excluding certain assets specifically retained by the Company). Such assets sold in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all right, title and interest in and to the Product, as specified in the Purchase Agreement.

In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately \$80.6 million after adjustments based on inventory being transferred and an advance of \$3 million of guaranteed earnout payments as part of the CRG settlement (described below in Item 3 – Legal Proceedings), (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414’s right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG (described above).

Upon closing of the Asset Sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect. At the closing of the Asset Sale, Cardinal Health 414 paid to the Company \$1.2 million, as an estimate of the accrued revenue sharing payments owed to the Company as of the closing date, net of prior payments. Post-closing and after paying off our outstanding indebtedness and transaction-related expenses, Navidea had approximately \$15.6 million in cash and \$3.7 million in payables, a large portion of which is tied to the 4694 program which Navidea is seeking to divest in the near term. Thus, the completion of the Asset Sale significantly improved our financial condition and our ability to continue as a going concern.

Summary

Our future liquidity and capital requirements will depend on a number of factors, including the final outcome of the CRG litigation which could potentially result in payment of up to an additional \$7 million to CRG, our ability to achieve market acceptance of our products, our ability to complete the development and commercialization of new products, our ability to monetize our investment in non-core technologies, our ability to obtain milestone or development funds from potential development and distribution partners, regulatory actions by the FDA and international regulatory bodies, the ability to procure required financial resources, and intellectual property protection.

Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern has been removed. The Company is also working to establish additional sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to sustainable levels. Substantial progress on the Manocept platform has resulted in several promising opportunities, including the formation of Macrophage Therapeutics, Inc. in January 2015.

We plan to focus our resources for 2017 primarily on transitioning the Business to Cardinal Health 414, defending our position related to CRG's claims of default, and development of products based on the Manocept platform. Although management believes that it will be able to achieve these objectives, they are subject to a number of variables beyond our control, including the outcome of the remaining CRG litigation, the nature and timing of any partnering opportunities, the ability to modify contractual commitments made in connection with these programs, and the timing and expense associated with suspension or alteration of clinical trials, and consequently there can be no assurance that we will be able to achieve our objective of bringing our expenses in line with our revenues, and we may need to seek additional debt or equity financing if we cannot achieve that objective in a timely manner.

During 2016 and 2015, we continued making limited investment in the NAV4694 clinical trial process based on our expectation that we will be successful in ultimately securing a partnership that will provide us some level of return on this investment which is incremental to the carrying costs we are presently incurring. However, there can be no assurance that the partnership discussions in which we are engaged will yield the level of return we are anticipating.

We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. There can be no assurance 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. Further, there can be no assurance that we will be able to gain access and/or be able to execute on securing new sources of funding, new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future. See Risk Factors.

Recent Accounting Standards

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, *Presentation of Financial Statements-Going Concern*. ASU 2014-15 defines when and how companies are required to disclose going concern uncertainties, which must be evaluated each interim and annual period. ASU 2014-15 requires management to determine whether substantial doubt exists regarding the entity's going concern presumption. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). If substantial doubt exists, certain disclosures are required; the extent of those disclosures depends on an evaluation of management's plans (if any) to mitigate the going concern uncertainty. ASU 2014-15 is effective prospectively for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption was permitted. The adoption of ASU 2014-15 did not have a material effect on our consolidated financial statements, however it may affect future disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We expect the adoption of ASU 2016-02 to result in an increase in right-of-use assets and lease liabilities on our consolidated statement of financial position related to our leases that are currently classified as operating leases, primarily for office space. Management is currently evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers – Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*. ASU 2016-08 does not change the core principle of the guidance, rather it clarifies the implementation guidance on principal versus agent considerations. ASU 2016-08 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-08 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We will evaluate the potential impact that the adoption of ASU 2014-09 may have on our consolidated financial statements following the closing of the Asset Sale to Cardinal Health 414 in March 2017.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the simplified areas apply only to nonpublic entities. ASU 2016-09 is effective for public business entities for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period. If an entity early adopts ASU 2016-09 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. Methods of adoption vary according to each of the amendment provisions. Management is currently evaluating the impact that the adoption of ASU 2016-09 will have on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers – Identifying Performance Obligations and Licensing*. ASU 2016-10 does not change the core principle of the guidance, rather it clarifies the identification of performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. ASU 2016-10 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-10 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We will evaluate the potential impact that the adoption of ASU 2016-10 may have on our consolidated financial statements following the closing of the Asset Sale to Cardinal Health 414 in March 2017.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers – Narrow-Scope Improvements and Practical Expedients*. ASU 2016-12 does not change the core principle of the guidance, rather it affects only certain narrow aspects of Topic 606, including assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. ASU 2016-12 affects the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-12 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We will evaluate the potential impact that the adoption of ASU 2016-12 may have on our consolidated financial statements following the closing of the Asset Sale to Cardinal Health 414 in March 2017.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 addresses certain specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement cash flows. ASU 2016-15 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted in any interim or annual period. If an entity early adopts ASU 2016-15 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. ASU 2016-15 should be applied using a retrospective transition method to each period presented, with certain exceptions. We adopted ASU 2016-15 upon issuance, which resulted in debt prepayment costs being classified as financing costs rather than operating costs on the statement of cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows – Restricted Cash*. ASU 2016-18 requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash or equivalents. Therefore, restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts ASU 2016-18 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes the interim period. Following the payoff of our CRG debt and release of our restricted cash in March 2017, we do not expect the adoption of ASU 2016-18 to have a material effect on our consolidated financial statements.

In December 2016, the FASB issued ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*. ASU 2016-20 does not change the core principle of the guidance, rather it affects only certain narrow aspects of Topic 606, including loan guarantee fees, contract cost impairment testing, provisions for losses on construction- and production-type contracts, clarification of the scope of Topic 606, disclosure of remaining and prior-period performance obligations, contract modification, contract asset presentation, refund liability, advertising costs, fixed-odds wagering contracts in the casino industry, and cost capitalization for advisors to private and public funds. ASU 2016-20 affects the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-12 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We will evaluate the potential impact that the adoption of ASU 2016-20 may have on our consolidated financial statements following the closing of the Asset Sale to Cardinal Health 414 in March 2017.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business*. ASU 2017-01 provides a screen to determine when a set of assets and activities (collectively, a “set”) is not a business. The screen requires that when substantially all of the fair market value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, ASU 2017-01 (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output, and (2) removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those periods. ASU 2017-01 should be applied prospectively on or after the effective date. No disclosures are required at transition. Early adoption is permitted for certain transactions as described in ASU 2017-01. Management is currently evaluating the impact that the adoption of ASU 2017-01 will have on our consolidated financial statements

Critical Accounting Policies

Revenue Recognition. Prior to the Asset Sale to Cardinal Health 414 in March 2017, we generated 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. 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, however, we may allow returns in certain circumstances based on specific agreements.

We earned additional revenues based on a percentage of the actual net revenues achieved by Cardinal Health 414 on sales to end customers made during each fiscal year. The amount we charged Cardinal Health 414 related to end customer sales of Lymphoseek was subject to a retroactive annual adjustment. To the extent that we could reasonably estimate the end customer prices received by Cardinal Health 414, we recorded sales based upon these estimates at the time of sale. If we were unable to reasonably estimate end customer sales prices related to products sold, we recorded revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with Cardinal Health 414.

We also earn revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

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 paid and payments under the grants become contractually due. Lastly, we recognize revenues from the provision of services to R-NAV and its subsidiaries.

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, chemistry, manufacturing and control-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 record 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 Financial Instruments.* Certain of our notes payable are required to be recorded at fair value. The estimated fair value of our debt is calculated using a discounted cash flow analysis as well as a probability-weighted Monte Carlo simulation. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. For the debt recorded at fair value, 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 consolidated statements of operations.

Contractual Obligations and Commercial Commitments

The following table presents our contractual obligations and commercial commitments as of December 31, 2016.

Contractual Cash Obligations	Payments Due By Period						
	Total	2017	2018	2019	2020	2021	Thereafter
Purchase obligations	\$1,088,154	\$1,088,154	\$ —	\$ —	\$ —	\$ —	\$ —
Operating lease obligation	1,707,871	277,946	284,246	290,734	297,405	304,201	253,339
Principal and interest on short-term debt	315,610	315,610	—	—	—	—	—
Principal and interest on long-term debt ⁽¹⁾⁽²⁾	66,896,551	57,408,729	—	—	—	9,487,822	—
Total contractual cash obligations	<u>\$7,008,186</u>	<u>\$9,090,439</u>	<u>\$ 284,246</u>	<u>\$ 290,734</u>	<u>\$ 297,405</u>	<u>\$9,792,023</u>	<u>\$ 253,339</u>

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

(1) This amount includes interest accrued under the CRG Loan Agreement of approximately \$5.8 million, which is included in accrued liabilities and other as of December 31, 2016.

(2) This amount assumes that the balance ultimately determined to be due under the CRG Loan Agreement will not differ from the \$59 million paid at the closing of the Asset Sale to Cardinal Health 414 in March 2017.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of December 31, 2016, our \$1.5 million in unrestricted 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, 2016, the interest rate on certain of our debt obligations was the greater of: (a) the U.S. prime rate as reported in The Wall Street Journal plus 6.75%, (b) 10.0% and (c) the highest rate of interest payable pursuant to the CRG Term Loan plus 0.125%; all of the above rates reduced by 600 basis points (effective interest rate as of December 31, 2016 was 8.125%). Based on the effective rate of our variable-rate borrowings, which totaled approximately \$9.5 million at December 31, 2016, an immediate one percentage point increase or 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, 2016, 2015 and 2014, we recorded foreign currency transaction (losses) gains of approximately \$(12,000), \$41,000 and \$87,000, 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, several of which are based on a survey of peer group companies since the warrants are exercisable for common stock of a non-public subsidiary company. As of December 31, 2016, we had approximately \$63,000 of derivative liabilities recorded on our balance sheet related to outstanding MT warrants. Due to the relatively low valuation of the MT warrants, a hypothetical 50% change in our stock price would not have a material effect on the consolidated financial statements.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, and the related notes, together with the report of Marcum LLP dated March 31, 2017 and the report of BDO USA, LLP dated March 23, 2016, are set forth at pages F-1 through F-39 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 Interim Chief Operating 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, 2016. 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.

As described in the Management's Report on Internal Control Over Financial Reporting section below, we identified material weaknesses in the Company's internal control over financial reporting. As a result, our CEO and CFO concluded that our disclosure controls were not effective as of December 31, 2016. In light of the identification of these material weaknesses in internal control over financial reporting, the Company has performed additional internal procedures, including validating the completeness and accuracy of the underlying data used to prepare the financial statements and related disclosures prior to filing this Annual Report on Form 10-K.

These additional procedures have allowed us to conclude that, notwithstanding the material weaknesses in our internal control over financial reporting, the consolidated financial statements included in this report fairly present, in all material respects, the Company's consolidated financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

Our management, including our Chief Executive Officer and Interim Chief Operating 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.

Under the supervision and with the participation of our management, including the CEO and Interim COO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2016 based upon the criteria set forth in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. We have identified the following material weaknesses:

- The Company did not maintain adequate controls to ensure that information pertinent to the Company's operations were analyzed and communicated by and between financial and non-financial management personnel of the Company. Management has concluded that this control deficiency represented a material weakness.
 - The Company did not maintain effective oversight of the Company's external financial reporting and internal control over financial reporting by the Company's audit committee. Management has concluded that this control deficiency represented a material weakness.
-

There were no material adjustments to our current or previously filed interim consolidated financial statements during the year ended December 31, 2016 as a result of these material weaknesses. However, management believes there is a reasonable possibility that these control deficiencies, if uncorrected, could result in material misstatements in the annual or interim consolidated financial statements that would not be prevented or detected in a timely manner. Accordingly, we have determined that these control deficiencies constitute material weaknesses.

Because of these material weaknesses, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2016, based on criteria described in *Internal Control – Integrated Framework (2013)* issued by COSO. Marcum, LLP, our independent registered public accounting firm, has issued an adverse opinion covering our internal control over financial reporting, which begins on page 53.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2016, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Audit Committee of the
Board of Directors and Shareholders
of Navidea Biopharmaceuticals, Inc.

We have audited Navidea Biopharmaceuticals, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company'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." 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 of internal control over financial reporting 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 the 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 degree of compliance with the policies or procedures may deteriorate.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in "Management's Report on Internal Control Over financial Reporting":

- The Company did not maintain adequate controls to ensure that information pertinent to the Company's operations were analyzed and communicated by and between financial and non-financial management personnel of the Company.
- The Company did not maintain effective oversight of the Company's external financial reporting and internal control over financial reporting by the Company's audit committee.

These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the fiscal 2016 consolidated financial statements, and this report does not affect our report dated March 31, 2017.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Navidea Biopharmaceuticals, Inc. has not maintained effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet as of December 31, 2016, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended and our report dated March 31, 2017 expressed an unqualified opinion on those financial statements.

/s/ Marcum LLP

New Haven, CT
March 31, 2017

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)
Anthony S. Fiorino, M.D., Ph.D.	49	Audit
Michael M. Goldberg, M.D.	58	—
Mark I. Greene, M.D., Ph.D., FRCP	68	Compensation, Nominating and Governance
Y. Michael Rice	52	Audit (Chairman); Compensation, Nominating and Governance
Eric K. Rowinsky, M.D.	60	Audit; Compensation, Nominating and Governance (Chairman)

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 2017 Annual Meeting:

Michael M. Goldberg, M.D. has served as a director of Navidea since November 2013 and as President and CEO of Navidea since September 2016. Dr. Goldberg has been a Managing Partner of Montaur Capital Partners since January 2007. From 2007 to 2013 Dr. Goldberg managed a life science investment portfolio for Platinum Partners called Platinum-Montaur Life Sciences, LLC. Prior to that, Dr. Goldberg served as the Chief Executive Officer of Emisphere Technologies, Inc., from August 1990 to January 2007 and as its President from August 1990 to October 1995. He also served on Emisphere's board of directors from November 1991 to January 2007. Previous to that, Dr. Goldberg served as Vice President of The First Boston Corp., where he was a founding member of the Healthcare Banking Group. Dr. Goldberg has been a Director of Echo Therapeutics, Inc., AngioLight, Inc., Urigen Pharmaceuticals, Inc., Alliqua BioMedical, Inc., and ADVENTRX Pharmaceuticals, Inc. 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 I. Greene M.D., Ph.D., FRCP has served as a Director of Navidea since March 2016. Dr. Greene has been Director of the Division of Immunology, Department of Pathology at University of Pennsylvania School of Medicine since 1986. Dr. Greene was the Associate Director of the Division for Fundamental Research, University of Pennsylvania Cancer Center from 1987 to 2009 and has been the John Eckman Professor of Medical Science of the University of Pennsylvania School of Medicine since 1989. From 1980 to 1986 he served as an Associate Professor of both Harvard University and Harvard Medical School. His groundbreaking work in erbB receptor function led to the development of Herceptin (Genentech) and to the development of a proprietary method for the rapid, reliable design of allosteric inhibitors of receptors and enzymes. Dr. Greene currently serves as a Member of the Scientific Advisory Board of Navidea's subsidiary Macrophage Therapeutics. He previously served as a scientific advisor to Ception Therapeutics, Antisome PLC and Fulcrum Technologies and also served as a member of the Scientific Advisory Boards of Fulcrum Pharmaceuticals, Inc. and Tolerx, Inc. He previously served as an Emeritus Director of Emisphere Technologies, Inc. where he also served as a Director. Additionally, Dr. Greene previously served as a Director of Ribic Immunochem Research, Inc. and currently serves as a Director of Martell Biosystems, Inc. Dr. Greene has an outstanding record of contributions to cancer biology and drug discovery that is well-documented in over 400 publications. Dr. Greene is a recipient of many awards and patents and has collaborated with a number of pharmaceutical companies. He received his M.D. (1972) and Ph.D. (1977) from the University of Manitoba, Canada, became a Fellow of the Royal College in 1977 and then joined the faculty of Harvard Medical School in 1978.

Director whose term continues until the 2018 Annual Meeting:

Anthony S. Fiorino, M.D., Ph.D. has served as a Director of Navidea since March 2016. Dr. Fiorino has almost 20 years of experience in biotechnology finance and drug development. Since December 2015, he has been President and CEO of Triumvira Immunologics, located in Hamilton, Ontario, Canada and Hackensack, New Jersey. Prior to this he was Chief Executive Officer at BrainStorm Cell Therapeutics from June 2014 to November 2015. From January 2013 to May 2014, he was a Managing Director at Greywall Asset Management, a healthcare equity fund, and President and Managing Member of Alchimia Partners, his consulting firm, from February 2008 to December 2012. Dr. Fiorino was also Founder, President and CEO of EnzymeRx, where he led the acquisition of a late-stage pre-clinical biologic and the development of the compound through Phase 1/2 clinical trials and its subsequent sale to 3SBio. Before founding EnzymeRx, Dr. Fiorino worked as a biotechnology and pharmaceuticals analyst and portfolio manager at firms including JP Morgan, Citigroup, and Pequot Capital. Dr. Fiorino earned an M.D. (1996) and a Ph.D. (1995) from the Albert Einstein College of Medicine where he studied the differentiation of liver progenitor cells, a B.S. in Biology from the Massachusetts Institute of Technology (1989) and has authored over 20 publications in the medical and scientific literature.

Directors whose terms continue until the 2019 Annual Meeting:

Y. Michael Rice has served as a director of Navidea since May 2016. Mr. Rice is a founding partner of LifeSci Advisors, LLC and LifeSci Capital, LLC, companies which he co-founded in March 2010. Prior to co-founding LifeSci Advisors and LifeSci Capital, Mr. Rice was the co-head of health care investment banking at Canaccord Adams, where he was involved in debt and equity financing. Mr. Rice was also a Managing Director at ThinkEquity Partners where he was responsible for managing Healthcare Capital Markets, including the structuring and execution of numerous transactions. Prior to that, Mr. Rice served as a Managing Director at Banc of America serving large hedge funds and private equity healthcare funds. Previously, he was a Managing Director at JPMorgan/Hambrecht & Quist. Mr. Rice currently serves on the board of directors of RDD Pharma, a specialty pharmaceuticals company. Mr. Rice received a B.A. from the University of Maryland.

Eric K. Rowinsky, M.D. has served as a director of Navidea since July 2010. Dr. Rowinsky has served as Executive Chairman, President, and Head of the Scientific Advisory Board of RGenix, Inc. since June 2015. He has also been the Head of Research and Development, Executive Vice President, and Chief Medical Officer of Stemline Therapeutics, Inc. from 2012 to 2015, and was the Chief Executive Officer and Founder of Primrose Therapeutics from August 2010 to September 2011 at which time it was acquired. From 2005 to 2009, he served as the Chief Medical Officer and Executive Vice President of Clinical Development and Regulatory Affairs of ImClone Systems Incorporated, a life sciences company which was acquired by Eli Lilly. Prior to that, Dr. Rowinsky held several positions at the Cancer Therapy & Research Center's Institute of Drug Development, including Director of the Institute, Director of Clinical Research and SBC Endowed Chair for Early Drug Development, and concurrently served as Clinical Professor of Medicine in the Division of Medical Oncology at the University of Texas Health Science Center at San Antonio. Dr. Rowinsky was an Associate Professor of Oncology at the Johns Hopkins University School of Medicine and on active staff at the Johns Hopkins School of Medicine from 1987 to 1996. Dr. Rowinsky is currently a member of the boards of directors of Biogen Idec, Inc. and Fortress Biosciences, Inc., and has served on the board of directors of BIND Therapeutics, Inc., all publicly-held life sciences companies. He is also an Adjunct Professor of Medicine at New York University. Dr. Rowinsky has extensive research and drug development experience, oncology expertise, corporate strategy, and broad scientific and medical knowledge.

Executive Officers

In addition to Dr. Goldberg, 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.	70	Senior Vice President and Chief Scientific Officer
Jed A. Latkin	42	Interim Chief Operating Officer, Chief Financial Officer, Treasurer and Secretary
William J. Regan	65	Senior Vice President and Chief Compliance Officer

Frederick O. Cope, Ph.D., F.A.C.N., C.N.S., has served as Senior Vice President and Chief Scientific Officer of Navidea since May 2013. Previous to that, Dr. Cope served as Senior Vice President, Pharmaceutical Research and Clinical Development of Navidea from July 2010 to May 2013 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. Dr. Cope also served as head of the Cancer and AIDS product development and commercialization program for the ROSS/Abbott Laboratories division, and head of human and veterinary vaccine production and improvement group for Wyeth Laboratories. 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 and nominee for the European Association of Nuclear Medicine Marie Curie 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.

Jed A. Latkin has served as Interim Chief Operating Officer, Chief Financial Officer, Treasurer and Secretary of Navidea since April 2016. Mr. Latkin has more than twenty years of experience in the financial industry supporting many investments in major markets including biotechnology and pharmaceuticals. He most recently was employed by Nagel Avenue Capital, LLC since 2010 and in that capacity he provided contracted services as a Portfolio Manager, Asset Based Lending for Platinum Partners Value Arbitrage Fund L.P. Mr. Latkin has been responsible for a large diversified portfolio of asset based investments in varying industries, including product manufacturing, agriculture, energy, and healthcare. In connection with this role, he served as Chief Executive Officer of End of Life Petroleum Holdings, LLC and Black Elk Energy, LLC, Chief Financial Officer of Viper Powersports, Inc. and West Ventures, LLC, and Portfolio Manager of Precious Capital, LLC. Mr. Latkin served on the Board of Directors for Viper Powersports, Inc. from 2012 to 2013 and currently serves on the boards of directors of the Renewable Fuels Association and Buffalo Lake Advanced Biofuels. Mr. Latkin earned a B.A. from Rutgers University and a M.B.A. from Columbia Business School.

William J. Regan joined Navidea in October 2012 and currently serves as our Senior Vice President and Chief Compliance Officer. 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 led efforts to gain two major FDA label expansions for Tc 99m tilmanocept and in addition has obtained EU regulatory approval for Tc 99m tilmanocept during 2014. 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 serves on the Mass Down Syndrome Congress Business Advisory Council and is a Managing Board Director for Turner Hill LLC. Mr. Regan holds a B.A. in Chemistry from Rutgers University.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and greater than 10% stockholders, to file reports of ownership and changes in ownership of our securities with the Securities and Exchange Commission. Copies of the reports are required by SEC regulation to be furnished to us. Based on our review of these reports and written representations from reporting persons, we believe that all reporting persons complied with all filing requirements during the fiscal year ended December 31, 2016, except for: (1) Anthony S. Fiorino, M.D., Ph.D., Michael M. Goldberg, M.D., Mark I. Greene, M.D., Ph.D., FRCP, Y. Michael Rice, Eric K. Rowinsky, M.D., and Gordon A. Troup, who each had one late Form 4 filing related to restricted stock issued as part of the annual board retainer; (2) Anthony S. Fiorino, M.D., Ph.D. and Mark I. Greene, M.D., Ph.D., FRCP each had one late Form 3 filing related to their initial appointment to the Board of Directors; (3) Eric K. Rowinsky, M.D. had one late Form 4 filing related to stock issued in lieu of cash for payment of board retainers; and (4) Jed A. Latkin had one late Form 4 filing related to stock options issued in connection with his continued employment.

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 17 meetings in the fiscal year ended December 31, 2016, 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, except for Ricardo J. Gonzalez, who attended 73 percent of the aggregate number of meetings of the Board of Directors held during his time as a Board member. 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 then-current members of our Board of Directors attended the 2016 Annual Meeting of Stockholders in person, except for Mark I. Greene, M.D., Ph.D., FRCP.

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: Y. Michael Rice (Chairman), Anthony S. Fiorino, M.D., Ph.D., and Eric K. Rowinsky, M.D., each of whom is "independent" under Section 803A of the NYSE MKT Company Guide. The Board of Directors has determined that Y. Michael Rice 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 16 meetings in the fiscal year ended December 31, 2016. 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: Eric K. Rowinsky, M.D. (Chairman), Mark I. Greene, M.D., Ph.D., FRCP, and Y. Michael Rice. The CNG Committee held two meetings in the fiscal year ended December 31, 2016 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 periodically 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 executives 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 next three highest-paid executive officers (the Named Executive Officers). At the Annual Meeting of Stockholders held on July 17, 2014, approximately 74% 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 2015 or 2016. The CNG Committee will continue to consider the results of future say-on-pay votes when making future compensation decisions for the executive officers.

The CNG Committee believes that, given the increased responsibilities of the President and Chief Executive Officer related to the Company’s legal and financial difficulties at the time of his appointment, Dr. Goldberg’s compensation is commensurate with that of his predecessor.

Scope of Authority of the CNG Committee. The Board of Directors has authorized the CNG Committee to establish the compensation programs for all executive officers and to provide oversight for compliance with our compensation philosophy. The CNG Committee delegates the day-to-day administration of the compensation plans to management (except with respect to our executive officers), but retains responsibility for ensuring that the plan administration is consistent with the Company’s policies. Annually, the CNG Committee sets the compensation for our executive officers, including objectives and awards under incentive plans. The Chief Executive Officer provides input for the CNG Committee regarding the performance and appropriate compensation of the other officers. The CNG Committee gives considerable weight to the Chief Executive Officer’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 2015. No conflict of interest exists that would prevent Pearl Meyer from serving as independent consultant to the CNG Committee.

For fiscal 2015, Pearl Meyer performed a benchmark compensation review of our key executive positions, including our Named Executive Officers. Pearl Meyer utilized both published survey and proxy reported data from compensation peers, with market data aged to March 1, 2016 by an annualized rate of 3.0%, the expected pay increase in 2016 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 2015, the CNG Committee noted that our overall executive compensation was, in aggregate, below the 25th percentile for an established peer group of companies.

Peer Group Companies. In addition to independent survey analysis, in 2015 the CNG Committee also reviewed the compensation levels at specific competitive benchmark companies. With input from management, the CNG Committee chose the peer companies because they operate within the biotechnology industry, have market capitalization between \$100 million and \$500 million, have similar business models to our Company or have comparable key executive positions. While the specific plans for these companies may or may not be used, it is helpful to review their compensation data to provide benchmarks for the overall compensation levels that will be used to attract, hire, retain and motivate our executives.

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

Sangamo Biosciences, Inc.	ArQule, Inc.
Inovio Pharmaceuticals, Inc.	Galena Biopharma, Inc.
Geron Corporation	Keryx Biopharmaceuticals, Inc.
Rigel Pharmaceuticals, Inc.	BioTime, Inc.
OncoMed Pharmaceuticals, Inc.	Omeros Corporation
CTI BioPharma Corp.	Immunomedics, Inc.
Unilife Corporation	Nymox Pharmaceutical Corporation

Pearl Meyer and the CNG Committee used the publicly available compensation information for these companies to analyze our competitive position in the industry. Base salaries and short-term and long term incentive plans of the executives of these companies were reviewed 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 2015 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 2015, the CNG Committee considered published proxy data for similar positions at peer group companies. Base salaries for fiscal 2016 remained unchanged from 2015.

The following table shows the changes in base salaries for the Named Executive Officers that were approved for fiscal 2016 compared to the approved salaries for fiscal 2015:

Named Executive Officer	Fiscal 2016	Fiscal 2015	Change ^(b)
	Base Salary ^(a)	Base Salary	
Michael M. Goldberg, M.D. ^(c)	\$ 400,000	\$ —	N/A
Ricardo J. Gonzalez ^(d)	375,000	375,000	0.0%
Frederick O. Cope, Ph.D.	279,130	279,130	0.0%
Thomas J. Klima ^(e)	270,000	270,000	0.0%
Brent L. Larson ^(f)	260,000	260,000	0.0%
Jed A. Latkin ^(g)	300,000	—	N/A
William J. Regan	250,000	250,000	0.0%

- (a) The amount shown for fiscal 2016 is the approved annual salary of the Named Executive Officer in effect at the end of 2016. The actual amount paid to the Named Executive Officer during fiscal 2016 is shown under “Salary” in the Summary Compensation table below.
- (b) Due to the Company’s financial difficulties in 2015 and 2016, Named Executive Officers did not receive salary increases in 2016.
- (c) Dr. Goldberg was appointed President and Chief Executive Officer of the Company effective September 22, 2016.
- (d) Mr. Gonzalez separated from the Company effective May 13, 2016.
- (e) Mr. Klima separated from the Company effective March 8, 2017.
- (f) Effective May 9, 2016, Mr. Larson was approved for short term disability by the Company’s insurance carrier and ceased acting as Chief Financial Officer. Mr. Larson separated from the Company effective October 6, 2016.
- (g) Mr. Latkin was appointed Interim Chief Operating Officer and Chief Financial Officer of the Company effective April 21, 2016.

The CNG Committee has not approved any changes to base salaries of Named Executive Officers for fiscal 2017.

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.

For the Named Executive Officers, cash bonus targets remained the same for fiscal 2016 as those that were established for fiscal 2015:

Named Executive Officer	Target Cash Bonus	
	(% of Salary)	(\$ Amount)
Michael M. Goldberg, M.D. ^(a)	75.0%	\$ 300,000
Ricardo J. Gonzalez ^(b)	50.0%	187,500
Frederick O. Cope, Ph.D.	35.0%	97,696
Thomas J. Klima ^(c)	35.0%	94,500
Brent L. Larson ^(d)	35.0%	91,000
Jed A. Latkin ^(e)	0.0%	—
William J. Regan	35.0%	87,500

- (a) Dr. Goldberg was appointed President and Chief Executive Officer of the Company effective September 22, 2016. Any bonus awarded for fiscal 2016 will be pro-rated from Dr. Goldberg's effective date of employment.
- (b) Mr. Gonzalez separated from the Company effective May 13, 2016, therefore no bonus will be awarded to Mr. Gonzalez for fiscal 2015.
- (c) Mr. Klima separated from the Company effective March 8, 2017.
- (d) Effective May 9, 2016, Mr. Larson was approved for short term disability by the Company's insurance carrier and ceased acting as Chief Financial Officer. Mr. Larson separated from the Company effective October 6, 2016, therefore no bonus will be awarded to Mr. Larson for fiscal 2016.
- (e) Mr. Latkin was appointed Interim Chief Operating Officer and Chief Financial Officer effective April 21, 2016. As an interim employee, Mr. Latkin's employment agreement does not provide for payment of a bonus.

The Board of Directors did not set specific bonus goals for fiscal 2016. On February 6, 2017, the Board of Directors determined the amounts to be awarded as 2016 bonuses to all employees, including the Named Executive Officers. The Board of Directors also determined that a portion of the 2016 bonus amount payable would be paid in stock in lieu of cash. The portion of the 2016 bonus amount payable in cash is either fifty percent or thirty-three percent, as determined by the Board of Directors. As such, Dr. Cope, Mr. Klima and Mr. Regan were awarded 70,492, 50,885 and 63,135, respectively, shares of common stock of the Company valued at \$0.52 per share, the closing price of Navidea's common stock on February 6, 2017. The cash portion of the 2016 bonus awards was paid on March 15, 2017. The Board of Directors has deferred determination of 2016 bonus awards to Dr. Goldberg and Mr. Latkin.

On February 25, 2016, the Board of Directors determined that fifty percent of the 2015 bonus amount payable to certain executive officers would be paid in stock options in lieu of cash, calculated based on the Black-Scholes value of the options on the date of grant. As such, Dr. Cope and Mr. Regan were awarded options to purchase 58,510 and 52,405, respectively, shares of common stock of the Company at an exercise price of \$0.98 per share, vesting immediately upon the date of grant and expiring after ten years. On February 6, 2017, the Board of Directors determined that the amounts previously awarded as 2015 bonuses would be subject to the same split between cash and stock as the 2016 bonus awards. As such, Dr. Cope and Mr. Regan were awarded an additional 17,886 and 16,020, respectively, shares of common stock of the Company valued at \$0.52 per share, the closing price of Navidea's common stock on February 6, 2017. The cash portion of the 2015 bonus awards was paid on March 15, 2017.

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.

Other Benefits and Perquisites. The Named Executive Officers are generally eligible to 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.

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 generally 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.
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Michael M. Goldberg, M.D. Dr. Goldberg is employed under a 12-month employment agreement effective through September 22, 2017. The employment agreement provides for an annual base salary of \$400,000, of which (i) \$300,000 shall be payable in semi-monthly installments of \$12,500, and (ii) \$100,000 shall be payable at such time as the Board determines in its sole discretion that the Company has adequate cash flow, subject to annual review and increase by the CNG Committee. For the calendar year ending December 31, 2016, the CNG Committee determined that the maximum bonus payment to Dr. Goldberg would be \$300,000, to be pro-rated based on time served during 2016. In connection with Dr. Goldberg's appointment as Chief Executive Officer of the Company, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of the 2016 Stock Incentive Plan. If approved, these stock options will vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant. If the 2016 Stock Incentive Plan is not approved, the Company will be obligated to pay in cash the implied market value of the options at the time of "exercise" by Dr. Goldberg, assuming the share price exceeds \$2.50 and all other vesting conditions are met.

Ricardo J. Gonzalez. Prior to his separation effective May 13, 2016, Mr. Gonzalez was employed under a 36-month employment agreement effective through October 13, 2017. The employment agreement provided for an annual base salary of \$375,000. For the calendar year ending December 31, 2016, the CNG Committee determined that the maximum bonus payment to Mr. Gonzalez would be \$187,500. Following his separation effective May 13, 2016, no bonus was awarded to Mr. Gonzalez for fiscal 2016.

Frederick O. Cope, Ph.D. Dr. Cope was employed under a 24-month employment agreement effective through December 31, 2014. The employment agreement provided for an annual base salary of \$271,000. Effective May 1, 2013, Dr. Cope's annual base salary was increased to \$279,130. For the calendar year ending December 31, 2016, the CNG Committee determined that the maximum bonus payment to Dr. Cope would be \$97,696. Although Dr. Cope's employment agreement expired on December 31, 2014, the terms of the agreement provide for continuation of certain terms of the employment agreement as long as Dr. Cope continues to be an employee of the Company following expiration of the agreement.

Thomas J. Klima. Mr. Klima was employed under a 24-month employment agreement effective through January 1, 2017. The employment agreement provided for an annual base salary of \$270,000. For the calendar year ending December 31, 2016, the CNG Committee determined that the maximum bonus payment to Mr. Klima would be \$94,500. The Company did not renew Mr. Klima's employment agreement, and Mr. Klima separated from the Company effective March 8, 2017.

Brent L. Larson. Mr. Larson was employed under a 24-month employment agreement effective through December 31, 2014. The employment agreement provided for an annual base salary of \$265,000. Effective May 1, 2013, Mr. Larson's annual base salary was increased to \$279,575. Effective January 1, 2014, Mr. Larson agreed to a reduction in his annual base salary to \$260,000. For the calendar year ending December 31, 2016, the CNG Committee determined that the maximum bonus payment to Mr. Larson would be \$91,000. Although Mr. Larson's employment agreement expired on December 31, 2014, the terms of the agreement provided for continuation of certain terms of the employment agreement as long as Mr. Larson continued to be an employee of the Company following expiration of the agreement. Effective October 6, 2016, Mr. Larson was approved for long term disability by the Company's insurance carrier and is accordingly no longer an employee of the Company. Following his separation effective October 6, 2016, no bonus was awarded to Mr. Larson for fiscal 2016.

Jed A. Latkin. Mr. Latkin is employed under an at-will employment agreement effective April 21, 2016. The employment agreement provides for a monthly base salary of \$15,000 during the first and second months of employment, \$17,500 during the third and fourth months of employment and \$20,000 per month thereafter. Effective October 21, 2016, Mr. Latkin's base salary was increased to \$25,000 per month. As an interim employee, Mr. Latkin's employment agreement does not provide for payment of a bonus.

William J. Regan. Mr. Regan was employed under a 15-month employment agreement effective through December 31, 2015. The employment agreement provided for an annual base salary of \$250,000. For the calendar year ending December 31, 2016, the CNG Committee determined that the maximum bonus payment to Mr. Regan would be \$87,500. Although Mr. Regan's employment agreement expired on December 31, 2015, the terms of the agreement provide for continuation of certain terms of the employment agreement as long as Mr. Regan continues to be an employee of the Company following expiration of the agreement.

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, 2016 and a stock price of \$0.64, our closing stock price on December 31, 2016.

Michael M. Goldberg, M.D. (e)

	For Cause	Resignation	Death	Disability	End of Term	Without Cause	Change in Control
Cash payments:							
Severance ^(a)	\$ —	\$ —	\$ —	\$ —	\$ 800,000	\$ 800,000	\$1,100,000
Disability supplement ^(b)	—	—	—	197,600	—	—	—
Paid time off ^(c)	7,692	7,692	7,692	7,692	7,692	7,692	7,692
Continuation of benefits ^(d)	—	—	26,858	26,858	—	—	—
Total	\$ 7,692	\$ 7,692	\$ 36,750	\$ 234,350	\$ 807,692	\$ 807,692	\$1,107,692

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

(b) During the first 6 months of disability, the Company will supplement disability insurance payments to Dr. Goldberg 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, 2016.

(d) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2016.

(e) Dr. Goldberg was appointed President and Chief Executive Officer of the Company effective September 22, 2016.

Frederick O. Cope, Ph.D.

	<u>For</u> <u>Cause</u>	<u>Resignation</u>	<u>Death</u>	<u>Disability</u>	<u>End of</u> <u>Term</u>	<u>Without</u> <u>Cause</u>	<u>Change in</u> <u>Control</u>
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
2016 401(k) match ^(d)	5,300	5,300	5,300	5,300	5,300	5,300	5,300
Continuation of benefits ^(e)	—	—	20,166	20,166	—	20,166	20,166
Stock option vesting acceleration ^(f)	—	—	—	—	—	—	—
Restricted stock vesting acceleration ^(g)	—	—	—	—	—	—	31,950
Total	\$ 10,668	\$ 10,668	\$ 30,834	\$ 167,999	\$ 255,668	\$ 275,834	\$ 430,284

(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, 2016.

(d) Amount represents the value of 6,375 shares of Company stock which was accrued during 2016 as the Company's 401(k) matching contribution but was unissued as of December 31, 2016.

(e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2016.

(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 \$0.64, the closing price of the Company's stock on December 31, 2016, less the exercise price of the options. Amount does not include stock options with an exercise price higher than \$0.64, the closing price of the Company's stock on December 31, 2016.

(g) Pursuant to Dr. Cope's restricted stock agreements, certain unvested restricted stock outstanding will vest upon a change in control. Amount represents the value of the stock at \$0.64, the closing price of the Company's stock on December 31, 2016, less the purchase price of the stock.

Thomas J. Klima ^(e)

	<u>For Cause</u>	<u>Resignation</u>	<u>Death</u>	<u>Disability</u>	<u>End of Term</u>	<u>Without Cause</u>	<u>Change in Control</u>
Cash payments:							
Disability supplement ^(a)	\$ —	\$ —	\$ —	\$ 132,600	\$ —	\$ —	\$ —
Paid time off ^(b)	5,192	5,192	5,192	5,192	5,192	5,192	5,192
Continuation of benefits ^(c)	—	—	14,529	14,529	—	—	—
Stock option vesting acceleration ^(d)	—	—	—	—	—	—	—
Total	<u>\$ 5,192</u>	<u>\$ 5,192</u>	<u>\$ 19,721</u>	<u>\$ 152,321</u>	<u>\$ 5,192</u>	<u>\$ 5,192</u>	<u>\$ 5,192</u>

- (a) During the first 6 months of disability, the Company will supplement disability insurance payments to Mr. Klima to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays \$100 per week for a maximum of 24 weeks.
- (b) Amount represents the value of 40 hours of accrued but unused vacation time as of December 31, 2016.
- (c) Amount represents 6 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2016.
- (d) Pursuant to Mr. Klima'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 \$0.64, the closing price of the Company's stock on December 31, 2016, less the exercise price of the options. Amount does not include stock options with an exercise price higher than \$0.64, the closing price of the Company's stock on December 31, 2016.
- (e) The Company did not renew Mr. Klima's employment agreement, and Mr. Klima separated from the Company effective March 8, 2017.

Jed A. Latkin ^(a)

	<u>For Cause</u>	<u>Resignation</u>	<u>Death</u>	<u>Disability</u>	<u>End of Term</u>	<u>Without Cause</u>	<u>Change in Control</u>
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

- (a) As an interim employee, Mr. Latkin's employment agreement does not provide for severance or any other post-employment benefits.

William J. Regan

	<u>For Cause</u>	<u>Resignation</u>	<u>Death</u>	<u>Disability</u>	<u>End of Term</u>	<u>Without Cause</u>	<u>Change in Control</u>
Cash payments:							
Severance ^(a)	\$ —	\$ —	\$ —	\$ —	\$ 250,000	\$ 250,000	\$ 375,000
Disability supplement ^(b)	—	—	—	122,600	—	—	—
Paid time off ^(c)	4,808	4,808	4,808	4,808	4,808	4,808	4,808
2016 401(k) match ^(d)	5,036	5,036	5,036	5,036	5,036	5,036	5,036
Continuation of benefits ^(e)	—	—	1,150	1,150	—	1,150	1,150
Stock option vesting acceleration ^(f)	—	—	—	—	—	—	—
Total	<u>\$ 9,844</u>	<u>\$ 9,844</u>	<u>\$ 10,993</u>	<u>\$ 133,593</u>	<u>\$ 259,844</u>	<u>\$ 260,993</u>	<u>\$ 385,993</u>

- (a) Severance amounts are pursuant to Mr. Regan's employment agreement.
- (b) During the first 6 months of disability, the Company will supplement disability insurance payments to Mr. Regan 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, 2016.
- (d) Amount represents the value of 6,015 shares of Company stock which was accrued during 2016 as the Company's 401(k) matching contribution but was unissued as of December 31, 2016.
- (e) Amount represents 12 months of dental and vision insurance premiums at rates in effect at December 31, 2016.
- (f) Pursuant to Mr. Regan'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 \$0.64, the closing price of the Company's stock on December 31, 2016, less the exercise price of the options. Amount does not include stock options with an exercise price higher than \$0.64, the closing price of the Company's stock on December 31, 2016.

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

Eric K. Rowinsky, M.D. (Chairman)

Mark I. Greene, M.D., Ph.D., FRCP

Y. Michael Rice

Compensation, Nominating and Governance Committee Interlocks and Insider Participation

The current members of our CNG Committee are: Eric K. Rowinsky, M.D. (Chairman), Mark I. Greene, M.D., Ph.D., FRCP, and Y. Michael Rice. During the fiscal year ended December 31, 2016, the members of our CNG Committee were: Anton Gueth (Chairman), Eric K. Rowinsky, M.D. (Chairman), Brendan A. Ford, Mark I. Greene, M.D., Ph.D., FRCP, Y. Michael Rice and Gordon A. Troup. None of these individuals were at any time during the fiscal year ended December 31, 2016, or at any other time, an officer or employee of the Company.

No director who served on the CNG Committee during 2016 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 2016.

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 2016

Named Executive Officer	Year	(c) Non-Equity Incentive Plan					(d) All Other Compensation	Total Compensation
		(a) Salary	(a) Stock Awards	(b) Option Awards	(c) Non-Equity Incentive Plan Compensation	(d) All Other Compensation		
Michael M. Goldberg ^(e) President and Chief Executive Officer	2016	\$ 83,077	\$ —	\$ —	\$ —	\$ 436	\$ 83,513	
	2015	—	—	—	—	—	—	
	2014	—	—	—	—	—	—	
Ricardo J. Gonzalez ^(f) President and Chief Executive Officer	2016	\$ 137,981	\$ —	\$ —	\$ —	\$ 3,352	\$ 141,333	
	2015	375,000	—	—	105,001	7,692	487,693	
	2014	82,452	—	768,247	16,241	—	866,940	
Frederick O. Cope, Ph.D. Senior Vice President and Chief Scientific Officer	2016	\$ 279,130	\$ —	\$ —	\$ 54,710	\$ 6,735	\$ 340,575	
	2015	279,130	—	155,026	54,709	6,657	495,522	
	2014	279,130	—	144,067	27,913	6,173	457,283	
Thomas J. Klima ^(g) Senior Vice President and Chief Commercial Officer	2016	\$ 270,000	\$ —	\$ —	\$ 52,920	\$ 2,326	\$ 325,246	
	2015	270,000	192,900	112,163	52,921	3,114	631,098	
	2014	—	—	—	—	—	—	
Brent L. Larson ^(h) Executive Vice President and Chief Financial Officer	2016	\$ 188,393	\$ —	\$ —	\$ —	\$ 5,826	\$ 194,219	
	2015	260,000	—	144,499	50,960	7,692	463,151	
	2014	260,000	—	134,318	17,875	6,727	418,920	
Jed A. Latkin ⁽ⁱ⁾ Interim Chief Operating Officer and Chief Financial Officer	2016	\$ 163,309	\$ —	\$ 39,992	\$ —	\$ —	\$ 203,301	
	2015	—	—	—	—	—	—	
	2014	—	—	—	—	—	—	
William J. Regan Senior Vice President and Chief Compliance Officer	2016	\$ 250,000	\$ —	\$ —	\$ 49,000	\$ 6,142	\$ 305,142	
	2015	250,000	—	157,896	49,001	6,410	463,307	
	2014	250,000	—	113,587	25,000	6,280	394,867	

- (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 total non-equity incentive plan amounts which have been approved by the Board of Directors as of the date this filing, and are disclosed for the year in which they were earned (i.e., the year to which the service relates).
- For 2016, the Board of Directors determined that a portion of the 2016 bonus amount payable would be paid in stock in lieu of cash. The portion of the 2016 bonus amount payable in cash is either fifty percent or thirty-three percent, as determined by the Board of Directors. As such, Dr. Cope, Mr. Klima and Mr. Regan were awarded 70,492, 50,885 and 63,135, respectively, shares of common stock of the Company valued at \$0.52 per share, the closing price of Navidea's common stock on February 6, 2017. Since these shares represent incentive compensation earned in 2016, they are reported in this column, and not included in the column "Stock Awards." The cash portion of the 2016 bonus awards was paid on March 15, 2017. The Board of Directors has deferred determination of 2016 bonus awards to Dr. Goldberg and Mr. Latkin.
 - For 2015, the Board of Directors initially determined that fifty percent of the 2015 bonus amount payable to certain executive officers would be paid in stock options in lieu of cash, calculated based on the Black-Scholes value of the options on the date of grant. As such, Dr. Cope, Mr. Klima, Mr. Larson and Mr. Regan were awarded, respectively, options to purchase 58,510, 56,598, 54,501 and 52,405 shares of common stock of the Company at an exercise price of \$0.98 per share, vesting immediately upon the date of grant and expiring after ten years. Since these options represent incentive compensation earned in 2015, they are reported in this column, and not included in the column "Option Awards." In February 2017, the Board of

Directors determined that the amounts previously awarded as 2015 bonuses would be subject to the same split between cash and stock as the 2016 bonus awards. As such, Dr. Cope and Mr. Regan were awarded an additional 17,886 and 16,020, respectively, shares of common stock of the Company valued at \$0.52 per share, the closing price of Navidea's common stock on February 6, 2017. Since these shares represent incentive compensation earned in 2015, they are reported in this column, and not included in the column "Stock Awards." The cash portion of the 2015 bonus awards was paid on March 15, 2017.

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

- (e) Dr. Goldberg commenced employment with the Company effective September 22, 2016. In connection with Dr. Goldberg's appointment as Chief Executive Officer of the Company, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of the 2016 Stock Incentive Plan. If approved, these stock options will vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant.
 - (f) Mr. Gonzalez commenced employment with the Company effective October 13, 2014 and separated from the Company effective May 13, 2016.
 - (g) Mr. Klima commenced employment with the Company effective January 1, 2015 and separated from the Company effective March 8, 2017.
 - (h) Mr. Larson was approved for long term disability by the Company's insurance carrier and separated from the Company effective October 6, 2016.
 - (i) Mr. Latkin commenced employment with the Company effective April 21, 2016.
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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 2016

Named Executive Officer	Year	(a) Reimbursement of Additional Tax Liability Related to Insurance Premiums		(b) 401(k) Plan Employer Matching Contribution		(c) Opt-Out Bonus		Total All Other Compensation
		\$		\$		\$		
Michael M. Goldberg, M.D.	2016	\$	436	\$	—	\$	—	\$ 436
	2015		—		—		—	—
	2014		—		—		—	—
Ricardo J. Gonzalez	2016	\$	836	\$	2,516	\$	—	\$ 3,352
	2015		2,392		5,300		—	7,692
	2014		—		—		—	—
Frederick O. Cope, Ph.D.	2016	\$	1,435	\$	5,300	\$	—	\$ 6,735
	2015		1,357		5,300		—	6,657
	2014		973		5,200		—	6,173
Thomas J. Klima	2016	\$	2,326	\$	—	\$	—	\$ 2,326
	2015		1,310		1,804		—	3,114
	2014		—		—		—	—
Brent L. Larson	2016	\$	2,007	\$	3,819	\$	—	\$ 5,826
	2015		2,392		5,300		—	7,692
	2014		1,527		5,200		—	6,727
Jed A. Latkin	2016	\$	—	\$	—	\$	—	\$ —
	2015		—		—		—	—
	2014		—		—		—	—
William J. Regan	2016	\$	106	\$	5,036	\$	1,000	\$ 6,142
	2015		110		5,300		1,000	6,410
	2014		80		5,200		1,000	6,280

- (a) 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.
- (b) 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.
- (c) Amount represents additional bonus paid for non-participation in the Company’s medical plan.

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 2016. 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 2016

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	All Other Option Awards: Number of Securities Underlying	Exercise Price of Option	Grant Date Fair Value of Stock and Option
		Threshold	Maximum	Threshold	Maximum				
Michael M. Goldberg, M.D. ^(d)	N/A	\$ —	\$ 83,013	—	—	—	—	\$ —	\$ — (a)
Ricardo J. Gonzalez	N/A	\$ —	\$ 187,500	—	—	—	—	\$ —	\$ — (a)
Frederick O. Cope, Ph.D.	N/A	\$ —	\$ 97,696	—	—	—	—	\$ —	\$ — (a)
Thomas J. Klima	N/A	\$ —	\$ 94,500	—	—	—	—	\$ —	\$ — (a)
Brent L. Larson	N/A	\$ —	\$ 91,000	—	—	—	—	\$ —	\$ — (a)
Jed A. Latkin	4/20/2016	\$ —	\$ —	—	—	—	45,000	\$ 1.50	\$ 29,339 (b)
	10/14/2016	\$ —	\$ —	—	—	—	20,000	\$ 1.00	\$ 10.653 (c)
William J. Regan	N/A	\$ —	\$ 87,500	—	—	—	—	\$ —	\$ — (a)

- (a) The threshold amount reflects the possibility that no cash bonus awards will be payable. The maximum amount reflects the cash bonus awards payable if the Board of Directors, in their discretion, awards the maximum cash bonus. The maximum cash bonus payable to Dr. Goldberg has been pro-rated beginning September 22, 2016. The Board of Directors has deferred determination of 2016 bonus awards to Dr. Goldberg and Mr. Latkin.
- (b) These stock options vested as to 7,500 options on the 20th day of each of the first six months following the date of grant, and expire on the tenth anniversary of the date of grant.
- (c) These stock options vested as to 10,000 options on the 20th day of each of the first two months following the date of grant, and expire on the tenth anniversary of the date of grant.
- (d) In connection with Dr. Goldberg’s appointment as Chief Executive Officer of the Company on September 22, 2016, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of the 2016 Stock Incentive Plan. If approved, these stock options will vest 100% when the average closing price of the Company’s common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant.

Outstanding Equity Awards

The following table presents certain information concerning outstanding equity awards held by the Named Executive Officers as of December 31, 2016.

Outstanding Equity Awards Table at Fiscal 2016 Year-End

Named Executive Officer	Option Awards					Stock Awards				
	Number of Securities Underlying Unexercised Options (#)		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	Equity Incentive Plan Awards		
	Exercisable	Unexercisable						Number of Unearned Shares	Market Value of Unearned Shares (v)	Note
Michael M. Goldberg, M.D.	—	5,000,000	\$ 1.00	9/22/2026	(p)			28,000	\$ 17,920	(r)
Ricardo J. Gonzalez (s)										
Frederick O. Cope, Ph.D.	50,000	—	\$ 0.65	2/16/2019	(c)			50,000	\$ 32,000	(q)
	75,000	—	\$ 1.10	10/30/2019	(d)					
	120,000	—	\$ 1.90	12/21/2020	(e)					
	127,000	—	\$ 3.28	2/17/2022	(g)					
	108,750	36,250	\$ 3.08	2/15/2023	(h)					
	66,500	66,500	\$ 1.77	1/28/2024	(i)					
	54,000	108,000	\$ 1.65	3/26/2025	(l)					
	58,510	—	\$ 0.98	2/25/2026	(m)					
Thomas J. Klima (t)	25,000	75,000	\$ 1.89	1/1/2025	(k)					
	56,598	—	\$ 0.98	2/25/2026	(m)					
Brent L. Larson (u)	50,000	—	\$ 0.36	1/3/2018	(a)					
	25,000	—	\$ 0.59	1/5/2019	(b)					
	75,000	—	\$ 1.10	10/30/2019	(d)					
	95,000	—	\$ 1.90	12/21/2020	(e)					
	88,000	—	\$ 3.28	2/17/2022	(g)					
	106,500	—	\$ 3.08	2/15/2023	(h)					
	62,000	—	\$ 1.77	1/28/2024	(i)					
	50,334	—	\$ 1.65	3/26/2025	(l)					
	54,501	—	\$ 0.98	2/25/2026	(m)					
Jed A. Latkin	45,000	—	\$ 1.50	4/20/2026	(n)					
	20,000	—	\$ 1.00	10/14/2026	(o)					
William J. Regan	20,000	—	\$ 3.29	7/1/2021	(f)					
	84,000	—	\$ 3.28	2/17/2022	(g)					
	75,000	25,000	\$ 3.08	2/15/2023	(h)					
	42,500	42,500	\$ 1.77	1/28/2024	(i)					
	12,500	12,500	\$ 1.50	12/17/2024	(j)					
	55,000	110,000	\$ 1.65	3/26/2025	(l)					
	52,405	—	\$ 0.98	2/25/2026	(m)					

- (a) Options were granted 1/3/2008 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (b) Options were granted 1/5/2009 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (c) Options were granted 2/16/2009 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (d) Options were granted 10/30/2009 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (e) Options were granted 12/21/2010 and vested as to one-fourth on each of the first four anniversaries of the date of grant.
- (f) Options were granted 7/1/2011 and vested as to one-fourth at the end of each of the first four quarters following the date of grant.
- (g) Options were granted 2/17/2012 and vested as to one-fourth on each of the first four anniversaries of the date of grant.
- (h) Options were granted 2/15/2013 and vest as to one-fourth on each of the first four anniversaries of the date of grant.
- (i) Options were granted 1/28/2014 and vest as to one-fourth on each of the first four anniversaries of the date of grant.
- (j) Options were granted 12/17/2014 and vest as to one-fourth on the date of grant, and one-fourth on January 28th of 2016, 2017 and 2018.
- (k) Options were granted 1/1/2015 and vest as to one-fourth on each of the first four anniversaries of the date of grant.
- (l) Options were granted 3/26/2015 and vest as to one-third on each of the first three anniversaries of the date of grant.
- (m) Options were granted 2/25/2016 and vested immediately. Options were granted in lieu of cash payment for fifty percent of the 2015 bonus payable to certain executive officers, calculated based on the Black-Scholes value of the options on the date of grant.
- (n) Options were granted 4/20/2016 and vested as to one-sixth on the 20th day of each of the first six months following the date of grant.

(o) Options were granted 10/14/2016 and vested as to one-half on the 20th day of each of the first two months following the date of grant.

- (p) Options were granted 9/22/2016 and vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, subject to stockholder approval of the 2016 Stock Incentive Plan.
- (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 April 20, 2016 in connection with Dr. Goldberg's service on the Company's Board of Directors. Pursuant to the terms of the restricted stock agreement between the Company and Dr. Goldberg, the restricted shares will vest on the first anniversary of the date of grant. If the employment of Dr. Goldberg 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. Goldberg's termination shall immediately be forfeited by Dr. Goldberg.
- (s) Mr. Gonzalez separated from the Company effective May 13, 2016. All of Mr. Gonzalez's stock options were forfeited as of the date of separation.
- (t) Mr. Klima separated from the Company effective March 8, 2017. All of Mr. Klima's stock options, if not exercised, will expire on June 6, 2017.
- (u) Mr. Larson was approved for long term disability by the Company's insurance carrier and separated from the Company effective October 6, 2016. All of Mr. Larson's stock options, if not exercised, will expire on October 6, 2017.
- (v) Estimated by reference to the closing market price of the Company's common stock on December 31, 2016, 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, 2016, was \$0.64.

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 2016.

Options Exercised and Stock Vested Table for Fiscal 2016

Named Executive Officer	Option Awards		Stock Awards		Note
	Number of Shares Acquired on Exercise	Value Realized on Exercise (a)	Number of Shares Acquired on Vesting	Value Realized on Vesting (a)	
Michael M. Goldberg, M.D.	—	\$ —	22,000	\$ 21,098	(b)
Ricardo J. Gonzalez	—	\$ —	—	\$ —	
Frederick O. Cope, Ph.D.	—	\$ —	—	\$ —	
Thomas J. Klima	—	\$ —	—	\$ —	
Brent L. Larson	50,000	\$ 23,000	—	\$ —	(c)
Jed A. Latkin	—	\$ —	—	\$ —	
William J. Regan	—	\$ —	—	\$ —	

- (a) Computed using the fair market value of the stock on the date prior to or the date of exercise or vesting, as appropriate, less the purchase price of the stock, in accordance with our normal practice.
- (b) On March 26, 2016, 22,000 shares of Dr. Goldberg's restricted stock vested in accordance with the terms of his restricted stock agreement. The market price on the last trading day prior to the vesting date was \$0.96 per share. This restricted stock was granted in connection with Dr. Goldberg's service on the Company's Board of Directors.
- (c) On December 8, 2016, Mr. Larson exercised 50,000 stock options in exchange for 50,000 shares of common stock. The market price on the last trading day prior to the exercise date was \$0.73 per share.

Compensation of Non-Employee Directors

Each non-employee director received an annual cash retainer of \$50,000 during the fiscal year ended December 31, 2016. The Chairman of the Company's Board of Directors received an additional annual retainer of \$30,000, 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 2016. We also reimbursed non-employee directors for travel expenses for meetings attended during 2016.

Each non-employee director also received 28,000 shares of restricted stock during 2016 as a part of the Company's annual stock incentive grants, in accordance with the provisions of the Navidea Biopharmaceuticals, Inc. 2014 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, 2017 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, 2016.

Name	(a) Fees Earned or Paid in Cash or Stock	(b),(c) Option Awards	(d),(e) Stock Awards	All Other Compensation	Total Compensation
	Anthony S. Fiorino, M.D., Ph.D. ^(f)	\$ 40,714	\$ —	\$ 36,652	\$ —
Brendan A. Ford ^(g)	14,251	—	—	—	97,448
Michael M. Goldberg, M.D. ^(h)	56,439	—	36,652	—	86,300
Mark I. Greene, M.D., Ph.D., FRCP ^(f)	40,714	—	36,652	—	
Anton Gueth ⁽ⁱ⁾	22,060	—	—	—	83,013
Y. Michael Rice ^(j)	38,322	—	17,665	—	66,042
Eric K. Rowinsky, M.D.	65,273	—	36,652	—	86,742
Gordon A. Troup ^(k)	17,761	—	36,652	—	107,523

- (a) Amount represents fees earned during the fiscal year ended December 31, 2016 (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.
- (c) At December 31, 2016, Dr. Rowinsky held 73,764 options to purchase shares of common stock of the Company.
- (d) Amount represents the aggregate grant date fair value in accordance with FASB ASC Topic 718.
- (e) During the year ended December 31, 2016, the non-employee directors were issued an aggregate of 168,000 shares of restricted stock which vest as to 100% of the shares on the first anniversary of the date of grant. At December 31, 2016, the non-employee directors held an aggregate of 129,000 shares of unvested restricted stock. Dr. Rowinsky held 45,000 shares of unvested restricted stock, and Drs. Fiorino and Greene and Mr. Rice each held 28,000 shares of unvested restricted stock.
- (f) Drs. Fiorino and Greene were appointed to the Board of Directors effective March 23, 2016.
- (g) Mr. Ford resigned from the Board of Directors effective March 23, 2016.
- (h) Dr. Goldberg was appointed President and CEO of the Company effective September 22, 2016, and therefore is no longer a non-employee director as of such date.
- (i) Mr. Gueth resigned from the Board of Directors effective March 31, 2016.
- (j) Mr. Rice was appointed to the Board of Directors effective May 4, 2016.
- (k) Mr. Troup resigned from the Board of Directors effective April 28, 2016.

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, 2016, 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.

	(1) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(2) Weighted- Average Exercise Price of Outstanding Options, Warrants and Rights	(3) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (1))
Equity compensation plans approved by security holders ^(a)	3,380,615	\$ 2.00	3,250,817
Equity compensation plans not approved by security holders ^(b)	—	—	—
Total	<u>3,380,615</u>	<u>\$ 2.00</u>	<u>3,250,817</u>

- (a) Our stockholders ratified the 2014 Stock Incentive Plan (the 2014 Plan) at the 2014 Annual Meeting of Stockholders held on July 17, 2014. The total number of shares available for awards under the 2014 Plan shall not exceed 5,000,000 shares, plus any shares subject to outstanding awards granted under prior plans and that expire or terminate for any reason. Although instruments are still outstanding under the Fourth Amended and Restated 2002 Stock Incentive Plan (the 2002 Plan), the plan has expired and no new grants may be made from it. The total number of securities to be issued upon exercise of outstanding options includes 1,349,401 issued under the 2014 Plan and 2,031,214 issued under the 2002 Plan.
- (b) In connection with Dr. Goldberg's appointment as Chief Executive Officer of the Company on September 22, 2016, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of the 2016 Stock Incentive Plan. If approved, these stock options will vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant.
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Security Ownership of Principal Stockholders, Directors, Nominees and Executive Officers and Related Stockholder Matters

The following table sets forth, as of February 28, 2017, 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.	963,853	(a)	— (n)
Anthony S. Fiorino, M.D., Ph.D.	28,000	(b)	— (n)
Michael M. Goldberg, M.D.	5,815,002	(c)	3.6%
Ricardo J. Gonzalez	—	(d)	— (n)
Mark I. Greene, M.D., Ph.D., FRCP	57,244	(e)	— (n)
Thomas J. Klima	158,533	(f)	— (n)
Brent L. Larson	979,619	(g)	— (n)
Jed A. Latkin	65,000	(h)	— (n)
William J. Regan	565,867	(i)	— (n)
Y. Michael Rice	—	(j)	— (n)
Eric K. Rowinsky, M.D.	298,210	(k)	— (n)
All directors and executive officers as a group (9 persons)	7,951,709	(l)(o)	4.9%
Platinum-Montaur Life Sciences, LLC	16,173,644	(m)	9.9%

- (*) 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, 2017, plus the number of shares the person has the right to acquire within 60 days of February 28, 2017.
- (a) This amount includes 783,260 shares issuable upon exercise of options which are exercisable within 60 days and 16,401 shares in Dr. Cope’s account in the 401(k) Plan, but it does not include 50,000 shares of unvested restricted stock and 87,250 shares issuable upon exercise of options which are not exercisable within 60 days.
- (b) This amount includes 28,000 shares of unvested restricted stock which are scheduled to vest within 60 days.
- (c) This amount includes 28,000 shares of unvested restricted stock which are scheduled to vest within 60 days, but it does not include 5,000,000 shares issuable upon exercise of options which are not exercisable within 60 days and are subject to stockholder approval of the 2016 Stock Incentive Plan. It also does not include any common stock to be issued upon exercise of the conversion rights related to the transfer to Dr. Goldberg of a 15% interest in the Platinum Loan Agreement pursuant to a Separation Agreement dated March 28, 2014, and amended effective June 11, 2015, between Dr. Goldberg and Platinum.
- (d) Mr. Gonzalez separated from the Company effective May 13, 2016. All of Mr. Gonzalez’s stock options were forfeited as of the date of separation.
- (e) This amount includes 28,000 shares of unvested restricted stock which are scheduled to vest within 60 days.
- (f) Mr. Klima separated from the Company effective March 8, 2017. This amount includes 106,598 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 50,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (g) Mr. Larson separated from the Company effective October 6, 2016. This amount is based on Mr. Larson’s most recent SEC ownership filings as well as the Company’s best knowledge and belief. This amount includes 606,335 shares issuable upon exercise of options which are exercisable within 60 days and 101,047 shares in Mr. Larson’s account in the 401(k) Plan.
- (h) This amount includes 65,000 shares issuable upon exercise of options which are exercisable within 60 days.
- (i) This amount includes 448,905 shares issuable upon exercise of options which are exercisable within 60 days and 7,807 shares in Mr. Regan’s account in the 401(k) Plan, but it does not include 82,500 shares issuable upon exercise of options which are not exercisable within 60 days.
- (j) This amount does not include 28,000 shares of unvested restricted stock.
- (k) This amount includes 28,000 shares of unvested restricted stock which are scheduled to vest within 60 days and 73,764 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 17,000 shares of unvested restricted stock.
- (l) This amount includes 112,000 shares of unvested restricted stock which are scheduled to vest within 60 days, 1,477,527 shares issuable upon exercise of options which are exercisable within 60 days, and 25,258 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 95,000 shares of unvested restricted stock and 5,219,750 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 241,333 shares of common stock.
- (m) The number of shares beneficially owned is based on a Schedule 13D/A filed by Platinum and certain of its affiliates with the Securities and Exchange Commission on June 28, 2016. This amount includes (i) 13,964,519 shares of our common stock, and (ii) 2,209,125 shares of common stock issuable upon exercise of Series LL warrants (the “Series LL Warrants”) at an exercise price of \$0.01 per share. The Series LL Warrants provide that the holder may not exercise any portion of the warrants to the extent that such 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 (the blocker). Accordingly, this amount excludes 2,156,155 shares of common stock underlying the Series LL Warrants that are subject to the blocker. The address of Platinum is 250 West 55th Street, 14th Floor, New York, NY 10019.
- (n) Less than one percent.

(o) 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 adopted a written policy regarding related party transactions in December 2015. When considering whether to enter into or ratify a related party transaction, the Audit Committee 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 must be approved or ratified by the Audit Committee.

SEC disclosure rules regarding transactions with related persons require the Company to provide information about transactions with directors and executive officers as a related persons, even though they may not have been related persons at the time the Company entered into the transactions described below.

Dr. Michael Goldberg, our President and Chief Executive Officer, previously managed a portfolio of funds for Platinum from May 2007 until December 2013. In 2011, he made an initial investment of \$1.5 million in PPVA as a passive investor. Dr. Goldberg believes his current investment balance is approximately \$1.4 million after giving effect to prior redemptions and reinvestments. Dr. Goldberg was not a member of the management of any of the Platinum entities; rather he solely had control over the trading activities of a portfolio of health care investments from funds allocated to him from the Platinum funds. Dr. Goldberg was responsible for all investments made by Platinum in the Company and for the trading in the Company's securities up until he joined the Company's Board of Directors in November 2013, at which time he relinquished all control over the trading of the Company's securities held by all of the Platinum entities. On December 13, 2013, Dr. Goldberg formally separated from Platinum and had no further role in managing their health care portfolio. As part of his separation from Platinum, Dr. Goldberg entered into a settlement agreement, dated March 28, 2014, and amended on June 11, 2015, with PPVA pursuant to which Dr. Goldberg was entitled to receive a beneficial ownership interest in 15% of (1) all securities held by Platinum at the time of his separation from Platinum which included, without limitation, warrants to purchase the Company's common stock, and (2) the drawn amounts from the Platinum debt facility. In furtherance of the foregoing, on October 17, 2016, Platinum transferred warrants to acquire an aggregate of 5,411,850 shares of our common stock to Dr. Goldberg, which warrants were exercised in full by Dr. Goldberg on January 17, 2017 resulting in gross proceeds to the Company of \$54,119.

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to PPCO an aggregate of approximately \$7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

If Dr. Goldberg is determined to be the owner of the remaining debt under the Platinum Loan Agreement, he has agreed to not require repayment by the Company of any debt transferred to him until the original maturity date of September 30, 2021, and has agreed to release any financial covenants and securitization requirements. The Company and Dr. Goldberg intend to finalize the negotiation of the definitive terms of such remaining indebtedness. Currently, the Company and Dr. Goldberg have not entered into a formal written agreement concerning the terms of such repayment. Pursuant to a settlement agreement, dated as of June 16, 2016, among the Company, PPVA, Platinum-Montaur Life Sciences, LLC and others, Platinum agreed to forgive interest owed on its credit facility with the Company in an amount equal to 6%, effective July 1, 2016, making the effective annual interest rate on the Platinum debt 8.125% as of December 31, 2016.

Jed A. Latkin, our Interim Chief Operating Officer and Chief Financial Officer, was an independent consultant that served as a portfolio manager from 2011 through 2015 for two entities, namely Precious Capital and West Ventures, each of which were during that time owned and controlled, respectively, by PPVA and Platinum Partners Capital Opportunities Fund, L.P. Mr. Latkin was party to a consulting agreement with each of Precious Capital and West Ventures pursuant to which, as of April 2015, an aggregate of approximately \$13 million was owed to him, which amount was never paid and Mr. Latkin has no information as to the current value. Mr. Latkin's consulting agreements were terminated upon his ceasing to be an independent consultant in April 2015 with such entities. During his consultancy, Mr. Latkin was granted a .5% ownership interest in each of Precious Capital and West Ventures, however, to his knowledge he no longer owns such interests. In addition, PPVA owes Mr. Latkin \$350,000 for unpaid consulting fees earned and expenses accrued in 2015 in respect of multiple consulting roles with them. Except as set forth above, Mr. Latkin has no other past or present affiliations with Platinum.

Dr. Eric Rowinsky, our current Chairman, was recommended for appointment to the Company's Board of Directors by Dr. Goldberg at a time when Dr. Goldberg was affiliated with Platinum and has, since that time, been elected by the Company's stockholders to continue to serve as an independent director. At no time has Dr. Rowinsky been affiliated, or in any way related to, any of the Platinum entities.

In March 2015, MT entered into an agreement to sell up to 50 shares of its MT Preferred Stock and warrants to purchase up to 1,500 shares of MT Common Stock to Platinum and Dr. Michael Goldberg for a purchase price of \$50,000 per share of MT Preferred Stock. On March 13, 2015, we announced that definitive agreements with the MT Investors had been signed for the sale of the first tranche of 10 shares of MT Preferred Stock and warrants to purchase 300 shares of MT Common Stock to the MT Investors, with gross proceeds to Macrophage Therapeutics of \$500,000. Under the agreement, 40% of the MT Preferred Stock and warrants are committed to be purchased by Dr. Goldberg, and the balance by Platinum. The full 50 shares of MT Preferred Stock and warrants to be sold under the agreement are convertible into and exercisable for MT Common Stock representing an aggregate 1% interest on a fully converted and exercised basis.

In addition, we entered into an Exchange Agreement with the MT Investors providing them an option to exchange their MT Preferred Stock for our common stock in the event that MT has not completed a public offering with gross proceeds to MT of at least \$50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing \$50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our common stock on the second anniversary of the initial closing or (ii) \$3.00. To the extent that the MT Investors do not timely exercise their exchange right, we have the right to redeem their MT Preferred Stock for a price equal to \$58,320 per share. We also granted MT an exclusive license for potential therapeutic applications of the Manocept technology.

During 2016, the largest aggregate amount of principal outstanding under the Platinum credit facility was \$9.5 million, and as of February 28, 2017, the amount of principal outstanding was \$9.6 million, including \$1.9 million of compounded interest.

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 Drs. Fiorino, Greene and Rowinsky, and Mr. Rice, meet the independence requirements.

Item 14. Principal Accountant Fees and Services

Audit Fees. The aggregate fees billed and expected to be billed for professional services rendered by Marcum LLP, primarily related to the audit of the Company's annual consolidated financial statements for the 2016 fiscal year, the audit of the Company's internal control over financial reporting as of December 31, 2016, and the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2016 fiscal year were \$331,627 (including direct engagement expenses).

The aggregate fees billed for professional services rendered by BDO USA, LLP, primarily related to the audit of the Company's annual consolidated financial statements for the 2015 fiscal year, the audit of the Company's internal control over financial reporting as of December 31, 2015, and the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2015 fiscal year were \$259,915 (including direct engagement expenses).

Audit-Related Fees. No fees were billed by Marcum LLP for audit-related services for the 2016 fiscal year. No fees were billed by BDO USA, LLP for audit-related services for the 2015 fiscal year.

Tax Fees. No fees were billed by Marcum LLP for tax-related services for the 2016 fiscal year. No fees were billed by BDO USA, LLP for tax-related services for the 2015 fiscal year.

All Other Fees. No fees were billed by Marcum LLP for services other than the audit, audit-related and tax services for the 2016 fiscal year. No fees were billed by BDO USA, LLP for services other than the audit, audit-related and tax services for the 2015 fiscal year.

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

PART IV

Item 15. Exhibits, Financial Statement Schedules

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:

Report of Independent Registered Public Accounting Firm – Marcum LLP	F-2
Report of Independent Registered Public Accounting Firm – BDO USA, LLP	F-4
Consolidated Balance Sheets as of December 31, 2016 and 2015	F-6
Consolidated Statements of Operations for the years ended December 31, 2016, 2015 and 2014	F-7
Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2016, 2015 and 2014	F-7
Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014	F-9
Notes to the Consolidated Financial Statements	F-11

(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, June 26, 2013 and August 18, 2016.*
3.2	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	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).
10.2	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).
10.3	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).
10.4	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).
10.5	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).
10.6	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).
10.7	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). ^
10.8	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). ^
10.9	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).
10.10	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).
10.11	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).

- 10.12 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).
- 10.13 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).
- 10.14 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).
- 10.15 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).
- 10.16 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).
- 10.17 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).
- 10.18 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).
- 10.19 Amended and Restated License Agreement, dated July 14, 2014, between the Company and the Regents of the University of California (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 Quarterly Report on Form 10-Q filed August 11, 2014).
- 10.20 Termination of License Agreement, dated July 14, 2014, between the Company and the Regents of the University of California (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed August 11, 2014).
- 10.21 License Agreement, dated July 14, 2014, between the Company and the Regents of the University of California (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 10.3 to the Company's Quarterly Report on Form 10-Q filed August 11, 2014).
- 10.22 Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan, adopted July 17, 2014 and amended March 3, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed May 11, 2015). ^
- 10.23 Form of Stock Option Agreement under the Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed November 10, 2014). ^
- 10.24 Form of Restricted Stock Award and Agreement under the Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 10, 2014). ^
- 10.25 Employment Agreement, dated October 13, 2014, between Navidea Biopharmaceuticals, Inc. and Ricardo J. Gonzalez (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 15, 2014). ^
- 10.26 Stock Option Agreement, dated October 13, 2014, between Navidea Biopharmaceuticals, Inc. and Ricardo J. Gonzalez (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed October 15, 2014). ^
- 10.27 Securities Exchange Agreement, dated November 12, 2014, by and between Navidea Biopharmaceuticals, Inc. 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 November 13, 2014).
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- 10.28 Employment Agreement between the Company and Thomas J. Klima, dated January 1, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed August 10, 2015).[^]
- 10.29 Employment Agreement between the Company and Michael Tomblyn, M.D., dated January 1, 2015 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed August 10, 2015).[^]
- 10.30 Securities Exchange Agreement dated as of March 11, 2015 among Macrophage Therapeutics, Inc., Platinum-Montaur Life Sciences, LLC and Michael Goldberg, M.D. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed May 11, 2015).
- 10.31 Navidea Biopharmaceuticals, Inc. 2015 Cash Bonus Plan adopted March 26, 2015 (incorporated by reference to the Company's Current Report on Form 8-K filed April 1, 2015).[^]
- 10.32 Termination Agreement, dated April 21, 2015, by and between Navidea Biopharmaceuticals, Inc. and Alseres Pharmaceuticals, 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 April 27, 2015).
- 10.33 Term Loan Agreement, dated as of May 8, 2015, by and among Navidea Biopharmaceuticals, Inc., as borrower, Macrophage Therapeutics, Inc. as guarantor, and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as lenders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed October 9, 2015).
- 10.34 Security Agreement, dated as of May 15, 2015 among Navidea Biopharmaceuticals, Inc., as borrower, Macrophage Therapeutics, Inc. as guarantor, and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as lenders, and Capital Royalty Partners II L.P., as control agent (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 15, 2015).
- 10.35 Subordination Agreement, dated as of May 8, 2015, among Platinum-Montaur Life Sciences, LLC, as subordinated creditor, Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as senior creditors, and Capital Royalty Partners II L.P., as senior creditor agent, and consented to by Navidea Biopharmaceuticals, Inc. as borrower (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 15, 2015).
- 10.36 Third Amendment to Loan Agreement, dated as of May 8, 2015, by and between Navidea Biopharmaceuticals, Inc. as borrower, and Platinum-Montaur Life Sciences, LLC, as lender (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed May 15, 2015).
- 10.37 Third Amended and Restated Promissory Note, dated May 8, 2015, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed May 15, 2015).
- 10.38 Securities Exchange Agreement, dated as of August 20, 2015, among the Company, Montsant Partners LLC 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 August 26, 2015).
- 10.39 Form of Series LL Warrant issued to Montsant Partners 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 August 26, 2015).
- 10.40 Amendment 1 to Term Loan Agreement by and among Navidea Biopharmaceuticals, Inc., as borrower, and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as lenders, dated as of December 23, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 11, 2016).
- 10.41 Agreement dated as of March 14, 2016 by and among the Company, Platinum Partners Value Arbitrage Fund L.P., Platinum Partners Liquid Opportunity Master Fund L.P., Platinum-Montaur Life Sciences, LLC, Platinum Management (NY) LLC, Platinum Liquid Opportunity Management (NY) LLC and Mark Nordlicht (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 18, 2016).
- 10.42 Director Agreement, dated March 15, 2016, by and between Navidea Biopharmaceuticals, Inc. and Mark I. Greene, M.D., Ph.D., FRCP (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed March 29, 2016).
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- 10.43 Director Agreement, dated March 17, 2016, by and between Navidea Biopharmaceuticals, Inc. and Anthony S. Fiorino, M.D., Ph.D. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed March 29, 2016).
- 10.44 Form of Director Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 10, 2016).
- 10.45 Employment Agreement, dated May 9, 2016 and effective as of April 21, 2016, between Navidea Biopharmaceuticals, Inc. and Jed A. Latkin (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed May 10, 2016). ^
- 10.46 Settlement Agreement, dated June 16, 2016, by and among Navidea Biopharmaceuticals, Inc., Platinum Partners Value Arbitrage Fund, L.P. and Platinum-Montaur Life Sciences, LLC, Cody Christopherson, and Hunter & Kmiec (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 29, 2016).
- 10.47 Employment Agreement, dated September 22, 2016, 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 September 27, 2016). ^
- 10.48 Asset Purchase Agreement, dated November 23, 2016, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 30, 2016).
- 10.49 Global Settlement Agreement dated March 3, 2017 by and among Navidea Biopharmaceuticals, Inc., Cardinal Health 414, LLC, Macrophage Therapeutics, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II (Cayman), L.P., Capital Royalty Partners II – Parallel Fund "A" L.P., Parallel Investment Opportunities Partners II L.P. and Capital Royalty Partners II – Parallel Fund "B" (Cayman) L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 8, 2017).
- 10.50 License-Back Agreement, dated March 3, 2017, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed March 8, 2017).
- 10.51 Warrant, dated March 3, 2017, issued to Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed March 8, 2017).
- 10.52 Warrant, dated March 3, 2017, issued to The Regents of the University of California (San Diego) (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed March 8, 2017).
- 10.53 Amended and Restated License Agreement, dated March 3, 2017, between Navidea Biopharmaceuticals, Inc. 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 Securities and Exchange Commission) (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed March 8, 2017).
- 21.1 Subsidiaries of the registrant.*
- 23.1 Consent of Marcum LLP.*
- 23.2 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 31, 2017

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)

By: /s/ Michael M. Goldberg
Michael M. Goldberg, M.D.
President and Chief Executive Officer

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

Signature	Title	Date
<u>/s/ Michael M. Goldberg</u> Michael M. Goldberg, M.D.	Director, President and Chief Executive Officer (principal executive officer)	March 31, 2017
<u>/s/ Jed A. Latkin*</u> Jed A. Latkin	Interim Chief Operating Officer and Chief Financial Officer (principal financial officer and principal accounting officer)	March 31, 2017
<u>/s/ Eric K. Rowinsky*</u> Eric K. Rowinsky, M.D.	Chairman, Director	March 31, 2017
<u>/s/ Anthony S. Fiorino*</u> Anthony S. Fiorino, M.D., Ph.D.	Director	March 31, 2017
<u>/s/ Mark I. Greene*</u> Mark I. Greene, M.D., Ph.D., FRCP	Director	March 31, 2017
<u>/s/ Y. Michael Rice*</u> Y. Michael Rice	Director	March 31, 2017

*By: /s/ Michael M. Goldberg
Michael M. Goldberg, M.D., Attorney-in-fact

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

NAVIDEA BIOPHARMACEUTICALS, INC.

FORM 10-K ANNUAL REPORT

As of December 31, 2016 and 2015
and for Each of the
Three Years in the Period Ended
December 31, 2016

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 – Marcum LLP	F-2
Report of Independent Registered Public Accounting Firm – BDO USA, LLP	F-4
Consolidated Balance Sheets as of December 31, 2016 and 2015	F-6
Consolidated Statements of Operations for the years ended December 31, 2016, 2015 and 2014	F-7
Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2016, 2015 and 2014	F-7
Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014	F-9
Notes to the Consolidated Financial Statements	F-11

Report of Independent Registered Public Accounting Firm

To the Audit Committee of the
Board of Directors and Shareholders of
Navidea Biopharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Navidea Biopharmaceuticals, Inc. (the "Company") as of December 31, 2016, and the related consolidated statements of operations, stockholders' deficit and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements 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 the consolidated financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Navidea Biopharmaceuticals, Inc. as of December 31, 2016, and the consolidated results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

We have also 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, 2016, based on the criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 31, 2017 expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting because of the existence of material weaknesses.

/s/ Marcum LLP

New Haven, Connecticut
March 31, 2017

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheet of Navidea Biopharmaceuticals, Inc. as of December 31, 2015 and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2015. 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, 2015, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Chicago, Illinois
March 23, 2016

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash	\$ 1,539,325	\$ 7,166,260
Restricted cash	5,001,253	—
Accounts and other receivables	1,802,010	3,703,186
Inventory, net	1,470,826	652,906
Prepaid expenses and other	1,012,855	1,054,822
Total current assets	<u>10,826,269</u>	<u>12,577,174</u>
Property and equipment	3,584,628	3,871,035
Less accumulated depreciation and amortization	<u>2,333,070</u>	<u>1,943,427</u>
	1,251,558	1,927,608
Patents and trademarks	202,194	233,596
Less accumulated amortization	<u>21,227</u>	<u>47,438</u>
	180,967	186,158
Other assets	202,882	273,573
Total assets	<u>\$ 12,461,676</u>	<u>\$ 14,964,513</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 7,123,323	\$ 1,767,523
Accrued liabilities and other	8,465,515	3,038,713
Deferred revenue, current	2,315,037	1,044,281
Notes payable, current	<u>51,957,913</u>	<u>333,333</u>
Total current liabilities	<u>69,861,788</u>	<u>6,183,850</u>
Deferred revenue	26,061	192,728
Notes payable, net of current portion and discounts of \$0 and \$2,033,506, respectively	9,641,179	60,746,002
Other liabilities	<u>598,861</u>	<u>1,677,633</u>
Total liabilities	<u>80,127,889</u>	<u>68,800,213</u>
Commitments and contingencies (Note 13)		
Stockholders' deficit:		
Preferred stock; \$.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at December 31, 2016 and 2015, respectively	—	—
Common stock; \$.001 par value; 300,000,000 shares authorized; 155,762,729 and 155,649,665 shares issued and outstanding at December 31, 2016 and 2015, respectively	155,763	155,650
Additional paid-in capital	326,564,148	326,085,743
Accumulated deficit	<u>(394,855,034)</u>	<u>(380,546,651)</u>
Total Navidea stockholders' deficit	<u>(68,135,123)</u>	<u>(54,305,258)</u>
Non-controlling interest	468,910	469,558
Total stockholders' deficit	<u>(67,666,213)</u>	<u>(53,835,700)</u>
Total liabilities and stockholders' deficit	<u>\$ 12,461,676</u>	<u>\$ 14,964,513</u>

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Operations

	Years Ended December 31,		
	2016	2015	2014
Revenue:			
Lymphoseek sales revenue	\$ 17,037,098	\$ 10,254,352	\$ 4,233,953
Lymphoseek license revenue	1,795,625	1,133,333	300,000
Grant and other revenue	3,136,983	1,861,622	1,740,896
Total revenue	<u>21,969,706</u>	<u>13,249,307</u>	<u>6,274,849</u>
Cost of goods sold	2,297,040	1,754,763	1,586,145
Gross profit	<u>19,672,666</u>	<u>11,494,544</u>	<u>4,688,704</u>
Operating expenses:			
Research and development	8,882,576	12,787,733	16,779,589
Selling, general and administrative	13,013,565	17,257,329	15,542,071
Total operating expenses	<u>21,896,141</u>	<u>30,045,062</u>	<u>32,321,660</u>
Loss from operations	<u>(2,223,475)</u>	<u>(18,550,518)</u>	<u>(27,632,956)</u>
Other income (expense):			
Interest expense, net	(14,861,270)	(6,873,736)	(3,690,068)
Equity in loss of R-NAV, LLC	(15,159)	(305,253)	(523,809)
Loss on disposal of investment in R-NAV, LLC	(39,732)	—	—
Change in fair value of financial instruments	2,858,524	(614,782)	(1,342,389)
Loss on extinguishment of debt	—	(2,440,714)	(2,610,196)
Other, net	(27,919)	26,808	72,749
Total other expense, net	<u>(12,085,556)</u>	<u>(10,207,677)</u>	<u>(8,093,713)</u>
Loss before income taxes	<u>(14,309,031)</u>	<u>(28,758,195)</u>	<u>(35,726,669)</u>
Benefit from income taxes	—	436,051	—
Loss from continuing operations	<u>(14,309,031)</u>	<u>(28,322,144)</u>	<u>(35,726,669)</u>
Income from discontinued operations, net of tax effect	—	758,609	—
Net loss	<u>(14,309,031)</u>	<u>(27,563,535)</u>	<u>(35,726,669)</u>
Less loss attributable to noncontrolling interest	(648)	(855)	—
Deemed dividend on beneficial conversion feature of MT Preferred Stock	—	(46,000)	—
Net loss attributable to common stockholders	<u><u>\$(14,308,383)</u></u>	<u><u>\$(27,608,680)</u></u>	<u><u>\$(35,726,669)</u></u>
(Loss) income per common share (basic and diluted):			
Continuing operations	\$ (0.09)	\$ (0.19)	\$ (0.24)
Discontinued operations	\$ —	\$ 0.01	\$ —
Attributable to common stockholders	\$ (0.09)	\$ (0.18)	\$ (0.24)
Weighted average shares outstanding (basic and diluted)	155,422,384	151,180,222	148,748,396

See accompanying notes to consolidated financial statements.

Issued stock payment of	—	—	(256,000)	(256)	228	—	—	(28)
Board retainers	—	—	84,062	84	66,455	—	—	66,539
Issued stock to 401(k) Plan	—	—	67,002	67	120,733	—	—	120,800
Issued stock upon exercise of								
stock options, net	—	—	50,000	50	13,450	—	—	13,500
Stock compensation expense	—	—	—	—	277,539	—	—	277,539
Net loss	—	—	—	—	—	(14,308,383)	(648)	(14,309,031)
Balance, December 31, 2016	—	\$ —	<u>155,762,729</u>	<u>\$ 155,763</u>	<u>\$26,564,148</u>	<u>\$394,855,034</u>	<u>\$ 468,910</u>	<u>\$67,666,213</u>

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	\$(14,309,031)	\$(27,563,535)	\$(35,726,669)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization of property and equipment	496,178	562,468	487,906
Amortization of patents and trademarks	5,191	8,951	12,277
Loss on disposal and abandonment of assets	136,719	33,184	31,794
Gain on forgiveness of accounts payable	(85,355)	—	—
Change in inventory reserve	43,354	143,493	539,027
Amortization of debt discount and issuance costs	77,964	492,963	844,250
Debt discount and issuance costs written off	1,955,541	—	—
Prepayment premium and debt collection fees related to long term debt	2,923,271	—	—
Compounded interest on long term debt	1,561,568	2,048,960	—
Stock compensation expense	277,539	2,368,685	1,634,162
Equity in loss of R-NAV, LLC	15,159	305,253	523,809
Loss on disposal of investment in R-NAV, LLC	39,732	—	—
Change in fair value of financial instruments	(2,858,524)	614,782	1,342,389
Loss on extinguishment of debt	—	2,440,714	2,610,196
Issued stock to 401(k) plan for employer matching contributions	120,800	117,099	100,043
Extension of warrant expiration date	—	149,615	—
Issued warrants in connection with advisory services agreement	—	256,450	—
Value of restricted stock issued to directors	66,539	172,969	89,375
Other	(15,159)	(63,677)	(38,657)
Changes in operating assets and liabilities:			
Accounts and other receivables	1,882,855	(2,808,696)	334,082
Inventory	(861,274)	135,986	761,024
Prepaid expenses and other assets	187,379	263,915	(476,860)
Accounts payable	5,441,155	290,024	(944,850)
Accrued liabilities and other liabilities	5,351,090	(282,642)	(1,250,047)
Deferred revenue	1,104,089	1,237,009	—
Net cash provided by (used in) operating activities	<u>3,556,780</u>	<u>(19,076,030)</u>	<u>(29,126,749)</u>
Cash flows from investing activities:			
Purchases of equipment	(1,847)	(39,001)	(1,114,448)
Proceeds from sales of equipment	45,000	38,265	—
Patent and trademark costs	—	(27,092)	(77,184)
Investment in R-NAV, LLC	—	—	(333,334)
Payments on disposal of investment in R-NAV, LLC	(110,000)	—	—
Proceeds from disposal of investment in R-NAV, LLC	27,623	—	—
Net cash used in investing activities	<u>(39,224)</u>	<u>(27,828)</u>	<u>(1,524,966)</u>
Cash flows from financing activities:			
Proceeds from issuance of MT Preferred Stock and warrants	—	500,000	—
Payment of preferred stock issuance costs	—	(12,587)	—
Proceeds from issuance of common stock, net	13,640	65,975	87,984
Payment of tax withholdings related to stock-based compensation	—	(23,906)	(130,537)
Proceeds from notes payable	—	54,500,000	30,000,000
Payment of debt-related costs	(3,923,271)	(3,902,487)	(1,763,526)
Principal payments on notes payable	(231,453)	(30,333,333)	(25,000,000)
Restricted cash held for payment against debt	(5,001,253)	—	—
Payments under capital leases	(2,154)	(2,550)	(2,226)
Net cash (used in) provided by financing activities	<u>(9,144,491)</u>	<u>20,791,112</u>	<u>3,191,695</u>
Net (decrease) increase in cash	(5,626,935)	1,687,254	(27,460,020)
Cash, beginning of period	7,166,260	5,479,006	32,939,026
Cash, end of period	<u>\$ 1,539,325</u>	<u>\$ 7,166,260</u>	<u>\$ 5,479,006</u>

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 (NYSE MKT: NAVB), is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on our Manocept™ platform to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care.

Navidea’s Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Lymphoseek® (technetium Tc 99m tilmanocept) injection, the first product developed and commercialized by Navidea based on the platform. Building on the success of Tc 99m tilmanocept, the flexible and versatile Manocept 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.

On March 3, 2017, pursuant to an Asset Purchase Agreement dated November 23, 2016, (the “Purchase Agreement”), the Company completed its previously announced sale to Cardinal Health 414, LLC (“Cardinal Health 414”) of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer (the “Business”), including the Company’s radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration (“FDA”) and similar indications approved by the FDA in the future (the “Product”), in Canada, Mexico and the United States (the “Territory”) (giving effect to the License-Back described below and excluding certain assets specifically retained by the Company) (the “Asset Sale”). Such assets sold in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all right, title and interest in and to the Product, as specified in the Purchase Agreement (the “Acquired Assets”).

Upon closing of the Asset Sale, the Supply and Distribution Agreement, dated November 15, 2007 (as amended, the “Supply and Distribution Agreement”), between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect (other than any indemnification, payment, notification or data sharing obligations which survive the termination).

The Asset Sale to Cardinal Health 414 in March 2017 significantly improved our financial condition and our ability to continue as a going concern. The Company also continues working to establish new sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be supported by our revenues.

Other than Tc 99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, none of the Company’s drug product candidates have been approved for sale in any market.

In January 2015, Macrophage Therapeutics, Inc. (“MT”), a majority-owned subsidiary, was formed specifically to explore immunotherapeutic applications for the Manocept platform.

From our inception through August 2011, we also manufactured a line of gamma detection systems called the neoprobe® GDS system (the “GDS Business”). We sold the GDS Business to Devicor Medical Products, Inc. (“Devicor”) in August 2011. 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 through 2017. We recorded income of \$759,000, net of taxes, in 2015 related to royalty amounts earned based on 2015 GDS Business revenue. The royalty amount of \$1.2 million was offset by \$436,000 in estimated taxes which were allocated to discontinued operations, but were fully offset by the tax benefit from our net operating loss for 2015. We did not earn or receive any such royalty payments prior to 2015 or in 2016.

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 is completed.

In July 2011, we established a European business unit, Navidea Biopharmaceuticals Limited, to address international development and commercialization needs for our technologies, including Tc 99m tilmanocept. 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 subsidiaries, Navidea Biopharmaceuticals Limited and Cardiosonix Ltd, as well as those of our majority-owned subsidiary, Macrophage Therapeutics, Inc. (“MT”). All significant inter-company accounts were eliminated in consolidation. Prior to termination of Navidea’s joint venture with R-NAV, LLC (“R-NAV”), Navidea’s investment in R-NAV was being accounted for using the equity method of accounting and was therefore not consolidated. See Note 10.
- 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:** In accordance with current accounting standards, 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, restricted cash, accounts and other receivables, accounts payable, and accrued liabilities: The carrying amounts approximate fair value because of the short maturity of these instruments. At December 31, 2016, restricted cash represents the balance in an account that is under the control of Capital Royalty Partners II L.P. (“CRG”). See Note 12. At December 31, 2016, approximately \$894,000 of accounts payable was being disputed by the Company related to unauthorized expenditures by a former executive during the year ended December 31, 2016.
 - (2) Notes payable: The carrying value of our debt at December 31, 2016 and 2015 primarily consists of the face amount of the notes less unamortized discounts. At December 31, 2016 and 2015, 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. 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 consolidated statements of operations. At December 31, 2016, the fair value of our notes payable is approximately \$61.6 million, equal to the carrying value of \$61.6 million. At December 31, 2015, the fair value of our notes payable was approximately \$64.0 million, compared to the carrying value of \$61.1 million. See Notes 3 and 12.
 - (3) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. Derivative liabilities totaling \$63,000 as of December 31, 2016 and 2015 were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of December 31, 2016 and 2015 included volatility, a 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 3.
- e. Stock-Based Compensation:** At December 31, 2016, we have instruments outstanding under two stock-based compensation plans; the Fourth Amended and Restated 2002 Stock Incentive Plan (the “2002 Plan”) and the 2014 Stock Incentive Plan (the “2014 Plan”). Currently, under the 2014 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 12 million shares and 5 million shares, respectively. Although instruments are still outstanding under the 2002 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 date of the grant.
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Stock options granted under the 2002 Plan and the 2014 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 up to 90 days following 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.

In September 2016, the Board of Directors approved the 2016 Stock Incentive Plan (the "2016 Plan"), authorizing a total of 10 million shares. The 2016 Plan has not yet been approved by Navidea's stockholders. In connection with Dr. Goldberg's appointment as Chief Executive Officer of the Company in September 2016, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of the 2016 Plan. If approved, these stock options will vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant.

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 granted during the years ended December 31, 2016, 2015 and 2014 are noted in the following table:

	2016	2015	2014
Expected volatility	59%-75%	61%-64%	61%-67%
Weighted-average volatility	60%	62%	65%
Expected dividends	—	—	—
Expected term (in years)	5.0-6.0	5.1-6.3	5.3-7.4
Risk-free rate	1.2%-1.8%	1.5%-1.9%	1.6%-2.0%

The portion of the fair value of stock-based awards that is ultimately expected to vest is recognized as compensation 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. Stock-based awards that do not vest because the requisite service period is not met prior to termination result in reversal of previously recognized compensation cost. 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 and Other Receivables:** Accounts and other receivables 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 and other receivables and write off accounts when deemed uncollectible. See Note 6.
- 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 7.
- i. **Property and Equipment:** Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is generally computed using the straight-line method over the estimated useful lives of the depreciable assets. 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 8.
- 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. No impairment was recognized during the years ended December 31, 2016, 2015 or 2014. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.
- l. 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 20.
- m. 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.
- n. Revenue Recognition:** Prior to the Asset Sale to Cardinal Health 414 in March 2017, we generated revenue primarily from sales of Lymphoseek. Our standard shipping terms are free on board (FOB) shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment. 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, however, we may allow returns in certain circumstances based on specific agreements.

We earned additional revenues based on a percentage of the actual net revenues achieved by Cardinal Health 414 on sales to end customers made during each fiscal year. The amount we charged Cardinal Health 414 related to end customer sales of Lymphoseek was subject to a retroactive annual adjustment. To the extent that we could reasonably estimate the end-customer prices received by Cardinal Health 414, we recorded sales based upon these estimates at the time of sale. If we were unable to reasonably estimate end customer sales prices related to products sold, we recorded revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with Cardinal Health 414. During the years ended December 31, 2016 and 2015, approximately 99% of Lymphoseek sales were made to Cardinal Health 414.

We also earn revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. We received a non-refundable upfront cash payment of \$2.0 million from SpePharm AG upon execution of the SpePharm License Agreement in March 2015. We have determined that the license and other non-contingent deliverables do not have stand-alone value because the license could not be deemed to be fully delivered for its intended purpose unless we perform our other obligations, including specified development work. Accordingly, they do not meet the separation criteria, resulting in these deliverables being considered a single unit of account. As a result, revenue relating to the upfront cash payment was deferred and was being recognized on a straight-line basis over the estimated obligation period of two years. However, the remaining deferred revenue of \$417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, several months earlier than originally anticipated.

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 paid and payments under the grants become contractually due. Lastly, we recognized revenues from the provision of services to R-NAV and its subsidiaries through the termination of the R-NAV joint venture on May 31, 2016. See Note 10.

- o. 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 and control-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.
- p. Income Taxes:** Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2016 and 2015.

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, 2016 or 2015 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, 2016, tax years 2013-2016 remained subject to examination by federal and state tax authorities. See Note 17.

- q. Change in Accounting Principle:** In April 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability rather than as an asset. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 was effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption was permitted. Entities must apply the amendments in ASU 2015-03 on a retrospective basis. In 2015, the Company adopted ASU 2015-03. We have reflected all remaining unamortized costs as a reduction of the debt on the balance sheets as of December 31, 2016 and 2015, and will continue to do so in future periods. The adoption of ASU 2015-03 had no impact on the consolidated statements of operations, stockholders' deficit or cash flows.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes*. ASU 2015-17 eliminates the requirement to bifurcate deferred taxes between current and noncurrent on the balance sheet and requires that deferred tax assets and liabilities be classified as noncurrent on the balance sheet. ASU 2015-17 may be applied retrospectively or prospectively and early adoption is permitted. We early-adopted ASU 2015-17 as of December 31, 2015 and the statement of financial position as of this date reflects the revised classification of current deferred tax assets and liabilities as noncurrent. Adoption of ASU 2015-17 resulted in a retrospective reclassification between current deferred tax assets and noncurrent deferred tax assets.

- r. Recent Accounting Developments:** In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern*. ASU 2014-15 defines when and how companies are required to disclose going concern uncertainties, which must be evaluated each interim and annual period. ASU 2014-15 requires management to determine whether substantial doubt exists regarding the entity's going concern presumption. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). If substantial doubt exists, certain disclosures are required; the extent of those disclosures depends on an evaluation of management's plans (if any) to mitigate the going concern uncertainty. ASU 2014-15 is effective prospectively for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption was permitted. The adoption of ASU 2014-15 did not have any effect on our consolidated financial statements, however it does affect disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We expect the adoption of ASU 2016-02 to result in an increase in right-of-use assets and lease liabilities on our consolidated statement of financial position related to our leases that are currently classified as operating leases, primarily for office space. Management is currently evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers – Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*. ASU 2016-08 does not change the core principle of the guidance, rather it clarifies the implementation guidance on principal versus agent considerations. ASU 2016-08 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-08 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We will evaluate the potential impact that the adoption of ASU 2014-09 may have on our consolidated financial statements following the closing of the Asset Sale to Cardinal Health 414 in March 2017.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the simplified areas apply only to nonpublic entities. ASU 2016-09 is effective for public business entities for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period. If an entity early adopts ASU 2016-09 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. Methods of adoption vary according to each of the amendment provisions. Management is currently evaluating the impact that the adoption of ASU 2016-09 will have on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers – Identifying Performance Obligations and Licensing*. ASU 2016-10 does not change the core principle of the guidance, rather it clarifies the identification of performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. ASU 2016-10 clarifies the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-10 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We will evaluate the potential impact that the adoption of ASU 2016-120 may have on our consolidated financial statements following the closing of the Asset Sale to Cardinal Health 414 in March 2017.

In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers – Narrow-Scope Improvements and Practical Expedients*. ASU 2016-12 does not change the core principle of the guidance, rather it affects only certain narrow aspects of Topic 606, including assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. ASU 2016-12 affects the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-12 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We will evaluate the potential impact that the adoption of ASU 2016-12 may have on our consolidated financial statements following the closing of the Asset Sale to Cardinal Health 414 in March 2017.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 addresses certain specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement cash flows. ASU 2016-15 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted in any interim or annual period. If an entity early adopts ASU 2016-15 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. ASU 2016-15 should be applied using a retrospective transition method to each period presented, with certain exceptions. We adopted ASU 2016-15 upon issuance, which resulted in debt prepayment costs being classified as financing costs rather than operating costs on the statement of cash flows for the year ended December 31, 2016.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows – Restricted Cash*. ASU 2016-18 requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash or equivalents. Therefore, restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts ASU 2016-18 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes the interim period. Following the payoff of our CRG debt and release of our restricted cash in March 2017, we do not expect the adoption of ASU 2016-18 to have a material effect on our consolidated financial statements.

In December 2016, the FASB issued ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*. ASU 2016-20 does not change the core principle of the guidance, rather it affects only certain narrow aspects of Topic 606, including loan guarantee fees, contract cost impairment testing, provisions for losses on construction- and production-type contracts, clarification of the scope of Topic 606, disclosure of remaining and prior-period performance obligations, contract modification, contract asset presentation, refund liability, advertising costs, fixed-odds wagering contracts in the casino industry, and cost capitalization for advisors to private and public funds. ASU 2016-20 affects the guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which is not yet effective. The effective date and transition requirements for ASU 2016-12 are the same as for ASU 2014-09, which was deferred by one year by ASU No. 2015-14, *Revenue from Contracts with Customers – Deferral of the Effective Date*. Public business entities should adopt the new revenue recognition standard for annual reporting periods beginning after December 15, 2017, including interim periods within that year. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that year. We will evaluate the potential impact that the adoption of ASU 2016-20 may have on our consolidated financial statements following the closing of the Asset Sale to Cardinal Health 414 in March 2017.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business*. ASU 2017-01 provides a screen to determine when a set of assets and activities (collectively, a “set”) is not a business. The screen requires that when substantially all of the fair market value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, ASU 2017-01 (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output, and (2) removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those periods. ASU 2017-01 should be applied prospectively on or after the effective date. No disclosures are required at transition. Early adoption is permitted for certain transactions as described in ASU 2017-01. Management is currently evaluating the impact that the adoption of ASU 2017-01 will have on our consolidated financial statements.

2. Liquidity

Prior to the Asset Sale to Cardinal Health 414 in March 2017, all of our material assets, except our intellectual property, were pledged as collateral for our borrowings under the Term Loan Agreement (the “CRG Loan Agreement”) with CRG. In addition to the security interest in our assets, the CRG Loan Agreement carried covenants that imposed significant requirements on us, including, among others, requirements that we (1) pay all principal, interest and other charges on the outstanding balance of the borrowed funds when due; (2) maintain liquidity of at least \$5 million during the term of the CRG Loan Agreement; and (3) meet certain annual EBITDA or revenue targets (\$22.5 million of Te 99m tilmanocept sales revenue in 2016) as defined in the CRG Loan Agreement. The events of default under the CRG Loan Agreement also included a failure of Platinum-Montaur Life Sciences LLC, an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P., Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, “Platinum”) to perform its funding obligations under the Platinum Loan Agreement (as defined below) at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum’s repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. An event of default would have entitled CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of \$4.1 million that was on deposit.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of the settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million (the "Deposit Amount") of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents (the "Final Payoff Amount"). The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million (the "Low Payoff Amount") and no more than \$66 million (the "High Payoff Amount"). In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The Company and CRG also agreed that the \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case would be released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7 million letter of credit, and on March 7, 2017, CRG posted a \$12 million letter of credit, each as required by the Global Settlement Agreement. See Notes 12 and 24(b).

In addition, our Loan Agreement with Platinum (the "Platinum Loan Agreement") carries standard non-financial covenants typical for commercial loan agreements, many of which are similar to those contained in the CRG 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, subject to the limitations of the Subordination Agreement with CRG. 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.

The Platinum Loan Agreement includes a covenant that results in an event of default on the Platinum Loan Agreement upon default on the CRG Loan Agreement. As discussed above, the Company is maintaining its position that CRG's alleged claims do not constitute events of default under the CRG Loan Agreement and believes it has defenses against such claims. The Company has obtained a waiver from Platinum confirming that we are not in default under the Platinum Loan Agreement as a result of the alleged default on the CRG Loan Agreement and as such, we are currently in compliance with all covenants under the Platinum Loan Agreement.

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to Platinum Partners Credit Opportunities Master Fund, LP ("PPCO") an aggregate of approximately \$7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur Life Sciences, LLC ("Platinum-Montaur"), which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by Platinum Partners Value Arbitrage Fund LP ("PPVA") that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA. See Notes 12 and 24(c).

Post-closing and after paying off our outstanding indebtedness and transaction-related expenses, Navidea has approximately \$15.6 million in cash and \$3.7 million in payables, a large portion of which is tied to the 4694 program which Navidea is seeking to divest in the near term. Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern has been removed. Although we could still be required to pay up to an additional \$7 million to CRG depending upon the outcome of the Texas litigation, the Company believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Annual Report on Form 10-K.

3. Fair Value

Platinum has the right to convert into common stock all or any portion of the unpaid principal or unpaid interest accrued on all draws under the Platinum credit facility, under certain circumstances. Platinum's debt instrument, including the embedded option to convert such debt into common stock, is recorded at fair value on the consolidated balance sheets and deemed to be a derivative instrument as the amount of shares to be issued upon conversion is indeterminable. The estimated fair value of the Platinum notes payable is \$9.6 million and \$11.5 million at December 31, 2016 and 2015, respectively.

MT issued warrants to purchase MT Common Stock with certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value on the consolidated balance sheets. The estimated fair value of the MT warrants is \$63,000 at both December 31, 2016 and 2015, and will continue to be measured on a recurring basis. See Notes 1(m) and 9.

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

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2016

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, 2016
Platinum notes payable	\$	—	\$	—	\$ 9,641,179	\$ 9,641,179
Liability related to MT warrants		—		—	63,000	63,000

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2015

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, 2015
Platinum notes payable	\$	—	\$	—	\$ 11,491,253	\$ 11,491,253
Liability related to MT warrants		—		—	63,000	63,000

- a. **Valuation Processes-Level 3 Measurements:** The Company utilizes third-party valuation services that use complex models such as Monte Carlo simulation to estimate the value of our financial liabilities. Each reporting period, the Company provides significant unobservable inputs to the third-party valuation experts based on current internal estimates and forecasts. The assumptions used in the Monte Carlo simulation as of December 31, 2016 and 2015 are summarized in the following table:

	2016	2015
Estimated volatility	76%	58%
Expected term (in years)	4.75	5.75
Debt rate	8.125%	14.125%
Beginning stock price	\$ 0.64	\$ 1.33

In addition, as of December 31, 2016 the Company estimated a 95% chance that the majority of the Platinum debt would be repaid in connection with the closing of the Asset Sale to Cardinal Health 414 during the first quarter of 2017.

- 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 certain liabilities. The significant unobservable inputs used in the fair value measurement of the liabilities include 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 paying off the debt prior to maturity. 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 or Level 2 liabilities outstanding at any time during the years ended December 31, 2016 and 2015. There were no transfers in or out of our Level 1 or Level 2 liabilities during the years ended December 31, 2016 and 2015. Changes in the estimated fair value of our Level 3 liabilities relating to unrealized gains (losses) are recorded as changes in fair value of financial instruments in the consolidated statements of operations. The change in the estimated fair value of our Level 3 liabilities during the years ended December 31, 2016, 2015 and 2014 was a decrease of \$2.9 million and increases of \$615,000 and \$1.3 million, respectively.

4. Stock-Based Compensation

For the years ended December 31, 2016, 2015 and 2014, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately \$278,000, \$2.4 million and \$1.6 million, respectively. We have not recorded any income tax benefit related to stock-based compensation for the years ended December 31, 2016, 2015 and 2014.

A summary of the status of our stock options as of December 31, 2016, and changes during the year then ended, is presented below:

	Year Ended December 31, 2016			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of year	5,437,064	\$ 1.96		
Granted	479,457	1.05		
Exercised	(50,000)	0.27		
Canceled and forfeited	(2,186,906)	1.69		
Expired	(299,000)	2.42		
Outstanding at end of year	<u>3,380,615</u>	<u>\$ 2.00</u>	6.5 years	<u>\$ 16,013</u>
Exercisable at end of year	<u>2,548,681</u>	<u>\$ 2.07</u>	6.1 years	<u>\$ 16,013</u>

The weighted average grant-date fair value of options granted in 2016, 2015, and 2014 was \$0.53, \$1.67 and \$1.56, respectively. During 2016, 50,000 stock options with an aggregate intrinsic value of \$23,000 were exercised in exchange for issuance of 50,000 shares of our common stock, resulting in gross proceeds of \$13,500. During 2015, 146,625 stock options with an aggregate intrinsic value of \$144,000 were exercised in exchange for issuance of 124,238 shares of our common stock, resulting in gross proceeds of \$66,000. During 2014, 468,000 stock options with an aggregate intrinsic value of \$582,000 were exercised in exchange for issuance of 299,360 shares of our common stock, resulting in gross proceeds of \$70,000. In 2016, 2015, and 2014, the aggregate fair value of stock options vested during the year was \$3,000, \$277,000 and \$4,000, respectively.

A summary of the status of our unvested restricted stock as of December 31, 2016, and changes during the year then ended, is presented below:

	Year Ended December 31, 2016	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of year	361,000	\$ 1.69
Granted	168,000	1.20
Forfeited	(206,000)	1.77
Expired	(50,000)	1.93
Vested	<u>(66,000)</u>	<u>1.65</u>
Unvested at end of year	<u>207,000</u>	<u>\$ 1.17</u>

During 2016, 2015 and 2014, 66,000, 333,250 and 216,250 shares, respectively, of restricted stock vested with aggregate vesting date fair values of \$63,000, \$511,000 and \$387,000, respectively.

In February 2016, 100,000 shares of restricted stock held by an executive officer with an aggregate fair value of \$96,000 were forfeited in connection with his separation from employment. During 2016, 66,000 shares of restricted stock held by non-employee directors with an aggregate fair value of \$63,000 vested as scheduled according to the terms of the restricted stock agreements. Also during 2016, 106,000 shares of restricted stock held by non-employee directors with an aggregate fair value of \$118,000 were forfeited as a result of their departures from the Board.

During 2015, 120,000 shares of restricted stock held by non-employee directors with an aggregate fair value of \$193,000 vested as scheduled according to the terms of the restricted stock agreements. Also during 2015, 193,250 shares of restricted stock held by employees with an aggregate fair value of \$286,000 vested as scheduled according to the terms of the restricted stock agreements. During 2015, 27,000 shares of restricted stock held by employees with an aggregate fair value of \$50,000 were forfeited in connection with their separation from employment. In April 2015, 20,000 shares of restricted stock held by an executive officer with an aggregate fair value of \$32,000 vested upon reaching a milestone as defined by the terms of the restricted stock agreement. In May 2015, 20,000 shares of restricted stock held by an executive officer with an aggregate fair value of \$25,000 were forfeited in connection with his separation from employment. In July 2015, 61,000 shares of restricted stock held by non-employee directors with an aggregate fair value of \$107,000 were forfeited as a result of their departures from the Board.

During 2014, 61,250 shares of restricted stock held by non-employee directors with an aggregate fair value of \$111,000 vested as scheduled according to the terms of the restricted stock agreements. Also during 2014, 40,000 shares of restricted stock held by executive officers with an aggregate fair value of \$52,000 vested upon reaching certain milestones as defined by the terms of the restricted stock agreements. In March 2014, 100,000 shares of restricted stock with an aggregate fair value of \$205,000 vested as scheduled according to the terms of the restricted stock agreement. In May 2014, 175,000 shares of restricted stock held by our former CEO with an aggregate fair value of \$278,000 were forfeited in connection with his separation from employment. In September 2014, 125,000 shares of restricted stock held by our former CEO with an aggregate fair value of \$166,000 were forfeited in connection with termination of his Consulting Agreement. In December 2014, 15,000 shares of restricted stock held by our former CEO with an aggregate fair value of \$19,000 vested as scheduled in accordance with the terms of the restricted stock agreement.

During 2015 and 2014, we paid minimum tax withholdings related to stock options exercised and restricted stock vested of \$24,000 and \$131,000, respectively. No such tax withholdings were paid related to stock options exercised or restricted stock vested during 2016. As of December 31, 2016, there was approximately \$223,000 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 1.2 years. See Note 1(e).

5. Earnings Per Share

Basic (loss) earnings per share is calculated by dividing net (loss) income 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 (loss) earnings 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 debt, convertible preferred stock, options and warrants.

The following table sets forth the calculation of basic and diluted (loss) earnings per share for the years ended December 31, 2016, 2015 and 2014:

	Years Ended December 31,		
	2016	2015	2014
Net loss	\$(14,039,031)	\$(27,563,535)	\$(35,726,669)
Less loss attributable to noncontrolling interest	(648)	(855)	—
Deemed dividend on beneficial conversion feature of MT Preferred Stock	—	(46,000)	—
Net loss attributable to common stockholders	<u>\$(14,308,383)</u>	<u>\$(27,608,680)</u>	<u>\$(35,726,669)</u>
Weighted average shares outstanding (basic and diluted)	155,422,384	151,180,222	148,748,396
Loss per common share (basic and diluted)	\$ (0.09)	\$ (0.18)	\$ (0.24)

Diluted (loss) earnings per common share for the years ended December 31, 2016, 2015 and 2014 excludes the effects of 14.1 million, 14.6 million and 19.0 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, 207,000, 361,000 and 498,250 shares of unvested restricted stock for the years ended December 31, 2016, 2015 and 2014, respectively, were excluded in determining basic and diluted loss per share because such inclusion would be anti-dilutive.

6. Accounts and Other Receivables and Concentrations of Credit Risk

Accounts and other receivables at December 31, 2016 and 2015 consist of the following:

	<u>2016</u>	<u>2015</u>
Trade	\$ 1,617,414	\$ 2,498,087
Other	184,596	1,205,099
	<u>\$ 1,802,010</u>	<u>\$ 3,703,186</u>

At December 31, 2016 and 2015, approximately 89% and 67%, respectively, of net accounts and other receivables were due from Cardinal Health 414. In addition, at December 31, 2015, approximately 32% of net accounts and other receivables were due from Devicor related to royalty amounts earned based on 2015 GDS Business revenue. As of December 31, 2016 and 2015, there was no allowance for doubtful accounts. We do not believe we are exposed to significant credit risk related to Cardinal Health 414 or Devicor 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.

7. Inventory

The components of net inventory at December 31, 2016 and 2015, net of reserves of \$0 and \$345,000, respectively, are as follows:

	<u>2016</u>	<u>2015</u>
Materials	\$ 658,650	\$ 330,000
Work-in-process	616,522	392,457
Finished goods	195,654	275,168
Reserves	—	(344,719)
	<u>\$ 1,470,826</u>	<u>\$ 652,906</u>

During 2016 and 2015, we utilized \$131,000 and \$446,000, respectively, of Tc 99m tilmanocept inventory for clinical study and product development purposes. Also during 2016 and 2015, we recorded obsolescence reserves of \$43,000 and \$52,000 of Tc 99m tilmanocept inventory related to specific lots that expired or were nearing product expiry and therefore were no longer expected to be sold. During 2016 and 2015, we wrote off \$0 and \$120,000, respectively, of materials related to production issues.

8. Property and Equipment

The major classes of property and equipment are as follows:

	<u>Useful Life</u>	<u>2016</u>	<u>2015</u>
Production machinery and equipment	5 years	\$ 1,163,252	\$ 1,427,472
Other machinery and equipment, primarily computers and research equipment	3 – 5 years	407,201	421,318
Furniture and fixtures	7 years	645,922	648,131
Software	3 years	470,669	476,530
Leasehold improvements*	Term of Lease	897,584	897,584
		<u>\$ 3,584,628</u>	<u>\$ 3,871,035</u>

* 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 of equipment under capital leases with accumulated amortization of \$7,000 at December 31, 2015. No property or equipment was under capital lease at December 31, 2016. During 2016, 2015 and 2014, we recorded \$496,000, \$562,000 and \$488,000, respectively, of depreciation and amortization related to property and equipment.

9. Investment in Macrophage Therapeutics, Inc.

In March 2015, MT, our previously wholly-owned subsidiary, entered into a Securities Purchase Agreement to sell up to 50 shares of its Series A Convertible Preferred Stock (“MT Preferred Stock”) and warrants to purchase up to 1,500 common shares of MT (“MT Common Stock”) to Platinum and Dr. Michael Goldberg (collectively, the “MT Investors”) for a purchase price of \$50,000 per unit. A unit consists of one share of MT Preferred Stock and 30 warrants to purchase MT Common Stock. Under the agreement, 40% of the MT Preferred Stock and warrants are committed to be purchased by Dr. Goldberg, and the balance by Platinum. The full 50 shares of MT Preferred Stock and warrants that may be sold under the agreement are convertible into, and exercisable for, MT Common Stock representing an aggregate 1% interest on a fully converted and exercised basis. Navidea owns the remainder of the MT Common Stock. On March 11, 2015, definitive agreements with the MT Investors were signed for the sale of the first 10 shares of MT Preferred Stock and warrants to purchase 300 shares of MT Common Stock to the MT Investors, with gross proceeds to MT of \$500,000. The MT Common Stock held by parties other than Navidea is reflected on the consolidated balance sheets as a noncontrolling interest.

The warrants have certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value, with subsequent changes in fair value included in earnings. The fair value of the warrants was estimated to be \$63,000 at issuance and at December 31, 2015. See Notes 1(m) and 3. In addition, the MT Preferred Stock was immediately available for conversion upon issuance and includes a beneficial conversion feature, resulting in a deemed dividend of \$46,000 related to the beneficial conversion feature. Finally, certain provisions of the Securities Purchase Agreement obligate the MT Investors to acquire the remaining MT Preferred Stock and related warrants for \$2.0 million at the option of MT. The estimated relative fair value of this put option was \$113,000 at issuance based on the Black-Scholes option pricing model and is classified within stockholders' equity.

In addition, we entered into a Securities Exchange Agreement with the MT Investors providing them an option to exchange their MT Preferred Stock for our common stock in the event that MT has not completed a public offering with gross proceeds to MT of at least \$50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing \$50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our common stock on the second anniversary of the initial closing or (ii) \$3.00. To the extent that the MT Investors do not timely exercise their exchange right, MT has the right to redeem their MT Preferred Stock for a price equal to \$58,320 per share. We also granted MT an exclusive license for certain therapeutic applications of the Manocept technology.

In December 2015 and May 2016, Platinum contributed a total of \$200,000 to MT. MT was not obligated to provide anything in return, although it was considered likely that the MT Board would ultimately authorize some form of compensation to Platinum. During the year ended December 31, 2016, the Company recorded the entire \$200,000 as a current liability pending determination of the form of compensation.

In July 2016, MT's Board of Directors authorized modification of the original investments of \$300,000 by Platinum and \$200,000 by Dr. Goldberg to a convertible preferred stock with a 10% paid-in-kind ("PIK") coupon retroactive to the time the initial investments were made. The conversion price of the preferred will remain at the \$500 million initial market cap but a full ratchet was added to enable the adjustment of conversion price, warrant number and exercise price based on the valuation of the first institutional investment round. In addition, the MT Board authorized issuance of additional convertible preferred stock with the same terms to Platinum as compensation for the additional \$200,000 of investments made in December 2015 and May 2016. As of the date of filing of this Form 10-K, final documents related to the above transactions authorized by the MT Board have not been completed.

10. Investment in R-NAV, LLC

In July 2014, Navidea formed a joint enterprise with Essex Woodlands-backed Rheumco, LLC, to develop and commercialize radiolabeled diagnostic and therapeutic products for rheumatologic and arthritic diseases. The joint enterprise, called R-NAV, LLC, combined Navidea's proprietary Manocept CD206 macrophage targeting platform and Rheumco's proprietary Tin-117m radioisotope technology to focus on leveraging the platforms across several indications with high unmet medical need, including the detection and treatment of RA and veterinary osteoarthritis.

Both Rheumco and Navidea contributed licenses for intellectual property and technology to R-NAV in exchange for common units in R-NAV. The contributions of these licenses were recorded using the carryover basis. R-NAV was initially capitalized through a \$4.0 million investment from third-party private investors, and the technology contributions from Rheumco and Navidea. Navidea committed an additional \$1.0 million investment to be paid over three years, with \$333,334 in cash contributed at inception and a promissory note in the principal amount of \$666,666, payable in two equal installments on the first and second anniversaries of the transaction. A principal payment of \$333,333 was made on the note payable to R-NAV in July 2015. In exchange for its capital and in-kind investment, the Company received 3,500,000 Common Units and 1,000,000 Series A preferred units of R-NAV ("Series A Units"). The Company was to receive an additional 500,000 Series A Units for management and technical services associated with the programs described above performed by the Company for R-NAV pursuant to a services agreement.

Navidea initially owned approximately 33.7% of the combined entity. At December 31, 2015, Navidea owned approximately 27.3% of R-NAV. Joint oversight over certain aspects of R-NAV was shared between Navidea and the other investors; Navidea did not control the operations of R-NAV. Navidea had three-year call options to acquire, at its sole discretion, all of the equity of R-NAV's TcRA Imaging, Inc. subsidiary ("TcRA") for \$10.5 million prior to the launch of a Phase 3 clinical trial for its development program, and all of the equity of R-NAV's SnRA Theragnostics, Inc. subsidiary at fair value upon completion of radiochemistry and biodistribution studies for its development program.

Effective May 31, 2016, Navidea terminated its joint venture with R-NAV. Under the terms of the agreement, Navidea (1) transferred all of its shares of R-NAV, consisting of 1,500,000 Series A Preferred Units and 3,500,000 Common Units, to R-NAV; and (2) paid \$110,000 in cash to R-NAV. In exchange, R-NAV (1) transferred all of its shares of TcRA to Navidea, thereby returning the technology licensed to TcRA to Navidea; and (2) forgave the \$333,333 remaining on the promissory note. Neither Navidea nor R-NAV has any further obligations of any kind to either party. As a result of this transaction, the Company recognized a loss on disposal of the investment in R-NAV of \$39,732 during 2016.

Navidea's investment in R-NAV was being accounted for using the equity method of accounting. In accordance with current accounting guidance, the Company's initial contributions of cash and note payable totaling \$1.0 million were allocated between the investment in R-NAV and the call option on TcRA based on the relative fair values of the assets. As a result, we recorded an initial equity investment in R-NAV of \$727,000 and a call option asset of \$273,000 as non-current assets at the time of the initial investment. Navidea's equity in the loss of R-NAV was \$15,159, \$305,253 and \$523,809 for the years ended December 31, 2016, 2015 and 2014, respectively. Navidea's equity in the loss of R-NAV exceeded our initial investment in R-NAV. As such, the carrying value of the Company's investment in R-NAV was \$0 as of May 31, 2016.

The Company's obligation to provide \$500,000 of in-kind services to R-NAV was being recognized as those services were provided. The Company provided \$15,000, \$64,000 and \$39,000 of in-kind services during the years ended December 31, 2016, 2015 and 2014, respectively. As of May 31, 2016, the Company had \$383,000 of in-kind services remaining to provide under this obligation. This obligation ceased on May 31, 2016 under the terms of the agreement.

Navidea provided additional services to R-NAV in support of its development activities. Such services were immaterial to Navidea's overall operations. See Note 12.

11. Accounts Payable, Accrued Liabilities and Other

Accounts payable at December 31, 2016 and 2015 includes an aggregate of \$116,000 and \$7,000, respectively, due to related parties related to director fees and MT scientific advisory board fees.

Accrued liabilities and other, including an aggregate of \$106,000 and \$83,000 due to related parties related to director fees and MT scientific advisory board fees, at December 31, 2016 and 2015, respectively, consist of the following:

	<u>2016</u>	<u>2015</u>
Interest	\$ 5,756,519	\$ 478
Contracted services	1,341,601	1,887,281
Compensation	945,787	873,726
Royalties	139,957	175,679
Other	281,651	101,549
	<u>\$ 8,465,515</u>	<u>\$ 3,038,713</u>

12. Notes Payable

Platinum

In July 2012, we entered into an agreement with Platinum to provide us with a credit facility of up to \$50 million. Following the approval of Tc 99m tilmanocept, Platinum was committed under the terms of the agreement to extend up to \$35 million in debt financing to the Company. The agreement also provided for Platinum to extend an additional \$15 million on terms to be negotiated. Through June 25, 2013, we drew a total of \$8.0 million under the original facility.

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"). 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%; or (c) the highest rate of interest then payable pursuant to the GECC/MidCap Loan Agreement plus 0.125%. 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 \$2.0 million in cumulative revenues from sales or licensing of Tc 99m tilmanocept. Platinum's option to convert future draws into common stock was determined to meet the definition of a liability. The estimated fair value of the embedded conversion option is included in the carrying value of the new debt.

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 \$4.8 million, 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 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).

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%.

In May 2015, in connection with the execution of the CRG Loan Agreement (discussed below), the Company amended the existing Platinum credit facility to allow this facility to remain in place in a subordinated role to the CRG Loan (the “Third Platinum Amendment”). Among other things, the Third Platinum Amendment (i) extended the term of the Platinum Loan Agreement until a date six months following the maturity date or earlier repayment of the CRG Term Loan; (ii) changes the interest rate to the greater of (a) the United States prime rate as reported in The Wall Street Journal plus 6.75%, (b) 10.0% and (c) the highest rate of interest then payable pursuant to the CRG Term Loan plus 0.125%; (iii) requires such interest to compound monthly; and (iv) changes the provisions of the Platinum Loan Agreement governing Platinum’s right to convert advances into common stock of the Company. The Third Platinum Amendment provides for the conversion of all principal and interest outstanding under the Platinum Loan Agreement, but not until such time as the average daily volume weighted average price of the Company’s common stock for the ten preceding trading days exceeds \$2.53 per share. The Third Platinum Amendment became effective upon initial funding of the CRG Loan Agreement.

The Platinum Note is reflected on the consolidated balance sheets at its estimated fair value, which includes the estimated fair value of the embedded conversion option of \$153,000 at December 31, 2016. During the years ended December 31, 2016, 2015 and 2014, changes in the estimated fair value of the Platinum debt liability were a decrease of \$2.9 million, an increase of \$615,000 and an increase of \$1.3 million, respectively, and were recorded as non-cash changes in the fair value of financial instruments. The estimated fair value of the Platinum Note was \$9.6 million and \$11.5 million as of December 31, 2016 and 2015, respectively.

The Platinum Loan Agreement carries standard non-financial covenants typical for commercial loan agreements, many of which are similar to those contained in the CRG 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, subject to the limitations of the Subordination Agreement with CRG. 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. The Platinum Loan Agreement includes a covenant that results in an event of default on the Platinum Loan Agreement upon default on the CRG Loan Agreement. As discussed below, the Company is maintaining its position that CRG’s alleged claims do not constitute events of default under the CRG Loan Agreement and believes it has defenses against such claims. The Company has obtained a waiver from Platinum confirming that we are not in default under the Platinum Loan Agreement as a result of the alleged default on the CRG Loan Agreement and as such, we are currently in compliance with all covenants under the Platinum Loan Agreement.

The Platinum Loan Agreement, as amended, provides us with a credit facility of up to \$50 million. We drew a total of \$4.5 million and \$4.0 million under the credit facility in each of the years ended December 31, 2015 and 2013. We did not make any draws under the credit facility during the years ended December 31, 2016 and 2014. In addition, \$1.0 million and \$761,000 of interest was compounded and added to the balance of the Platinum Note during the years ended December 31, 2016 and 2015, respectively. In accordance with the terms of a Section 16(b) Settlement Agreement, Platinum agreed to forgive interest owed on the credit facility in an amount equal to 6%, effective July 1, 2016. As of December 31, 2016, the remaining outstanding principal balance of the Platinum Note was approximately \$9.5 million, consisting of \$7.7 million of draws and \$1.8 million of compounded interest, with \$27.3 million still available under the credit facility. An additional \$15 million is potentially available under the credit facility on terms to be negotiated. However, based on Platinum’s recent filing for Chapter 15 bankruptcy protection, Navidea has substantial doubt about Platinum’s ability to fund future draw requests under the credit facility.

In connection with the closing of the Asset Sale to Cardinal Health 414 in March 2017, the Company repaid to PPCO an aggregate of approximately \$7.7 million in partial satisfaction of the Company’s liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company’s President and Chief Executive Officer, and PPVA.

In May 2015, Navidea and MT, as guarantor, executed a Term Loan Agreement (the “CRG Loan Agreement”) with Capital Royalty Partners II L.P. (“CRG”) in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the “Lenders”) in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of \$50 million (the “CRG Term Loan”), with an additional \$10 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. Closing and funding of the CRG Term Loan occurred on May 15, 2015 (the “Effective Date”). The principal balance of the CRG Term Loan bore interest from the Effective Date at a per annum rate of interest equal to 14.0%. Through March 31, 2019, the Company had the option of paying (i) 10.00% of the per annum interest in cash and (ii) 4.00% of the per annum interest as compounded interest which is added to the aggregate principal amount of the CRG Term Loan. During 2016 and 2015, \$553,000 and \$1.3 million of interest was compounded and added to the balance of the CRG Term Loan. In addition, the Company began paying the cash portion of the interest in arrears on June 30, 2015. Principal was due in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, was due and payable in full on March 31, 2021.

Pursuant to a notice of default letter sent to Navidea by CRG in April 2016, the Company stopped compounding interest in the second quarter of 2016 and began recording accrued interest. As of December 31, 2016 and 2015, \$5.8 million and \$0, respectively, of accrued interest related to the CRG Term Loan is included in accrued liabilities and other on the consolidated balance sheets. As of December 31, 2016 and 2015, the outstanding principal balance of the CRG Term Loan was \$51.7 million and \$51.3 million, respectively.

In connection with the CRG Loan Agreement, the Company recorded a debt discount related to lender fees and other costs directly attributable to the CRG Loan Agreement totaling \$2.2 million, including a \$1.0 million facility fee which is payable at the end of the term or when the loan is repaid in full. A long-term liability was recorded for the \$1.0 million facility fee. The debt discount was being amortized as non-cash interest expense using the effective interest method over the term of the CRG Loan Agreement. As further described below, the facility fee was fully paid off and the debt discount was accelerated and fully amortized in the second quarter of 2016.

The CRG Term Loan was collateralized by a security interest in substantially all of the Company's assets. In addition, the CRG Loan Agreement required that the Company adhere to certain affirmative and negative covenants, including 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 CRG Loan Agreement. The Lenders could accelerate the payment terms of the CRG Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the CRG Loan Agreement, the failure of the Company to adhere to the covenants set forth in the CRG Loan Agreement, and the insolvency of the Company. The covenants of the CRG Loan Agreement included a covenant that the Company shall have EBITDA of no less than \$5 million in each calendar year during the term or revenues from sales of Tc 99m tilmanocept in each calendar year during the term of at least \$22.5 million in 2016, with the target minimum revenue increasing in each year thereafter until reaching \$45 million in 2020. However, if the Company were to fail to meet the applicable minimum EBITDA or revenue target in any calendar year, the CRG Loan Agreement provided the Company a cure right if it raised 2.5 times the EBITDA or revenue shortfall in equity or subordinated debt and deposited such funds in a separate blocked account. Additionally, the Company was required to maintain liquidity, defined as the balance of unencumbered cash and permitted cash equivalent investments, of at least \$5 million during the term of the CRG Term Loan. The events of default under the CRG Loan Agreement also included a failure of Platinum to perform its funding obligations under the Platinum Loan Agreement at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum's repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. An event of default would entitle CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of \$4.1 million that was on deposit, applying \$3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining \$189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million and no more than \$66 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The Company and CRG also agreed that the \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case would be released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7 million letter of credit, and on March 7, 2017, CRG posted a \$12 million letter of credit, each as required by the Global Settlement Agreement. The Texas hearing is currently set for July 3, 2017. See Notes 3, 13 and 24(b).

Oxford Finance, LLC

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 million, 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"). The Company recorded a debt discount related to the issuance of the Series KK Warrants and other fees to the lenders totaling \$3.0 million. Debt issuance costs directly attributable to the Oxford Loan Agreement, totaling \$120,000, were recorded as an additional debt discount on the consolidated balance sheet on the closing date. The debt discounts were being amortized as non-cash interest expense using the effective interest method over the term of the Oxford Loan Agreement. The final payment fee of \$2.4 million was recorded in other non-current liabilities on the consolidated balance sheet on the closing date.

We began making monthly payments of interest only on April 1, 2014, and monthly payments of principal and interest beginning April 1, 2015. In May 2015, in connection with the consummation of the CRG Loan Agreement, the Company repaid all amounts outstanding under the Oxford Loan Agreement. The payoff amount of \$31.7 million included payments of \$289,000 as a pre-payment fee and \$2.4 million as an end-of-term final payment fee. As of December 31, 2015, the Oxford Notes were no longer outstanding. The Series KK warrants remained outstanding as of December 31, 2016.

General Electric Capital Corporation/MidCap Financial SBIC, LP

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"), pursuant to which 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 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 GECC/MidCap Notes 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 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 totaled \$881,000. The debt discount and debt issuance costs were being amortized as non-cash interest expense using the effective interest method over the term of the GECC/MidCap Loan Agreement. The final payment fee of \$1.0 million was recorded in other non-current liabilities on the consolidated balance sheet on the closing date.

In March 2014, in connection with the consummation of the Oxford Loan Agreement, we repaid all amounts outstanding under the GECC/MidCap Notes for a payoff amount of \$26.7 million, which included payments of \$500,000 as a pre-payment fee and \$1.0 million as an end-of-term final payment fee, resulting in a loss on extinguishment of \$2.6 million. As of December 31, 2014, the GECC/MidCap Notes were no longer outstanding. The Series HH Warrants remained outstanding as of December 31, 2016.

R-NAV, LLC

In July 2014, in connection with entering into the R-NAV joint enterprise, Navidea executed a promissory note in the principal amount of \$666,666, payable in two equal installments on July 15, 2015 and July 15, 2016, the first and second anniversaries of the R-NAV transaction. The note bore interest at 0.31% per annum, compounded annually. A principal payment of \$333,333 was made on the note payable to R-NAV in July 2015.

Effective May 31, 2016, Navidea terminated its joint venture with R-NAV. Under the terms of the agreement, Navidea (1) transferred all of its shares of R-NAV, consisting of 1,500,000 Series A Units and 3,500,000 Common Units, to R-NAV; and (2) paid \$110,000 in cash to R-NAV. In exchange, R-NAV (1) transferred all of its shares of TcRA to Navidea, thereby returning the technology licensed to TcRA to Navidea; and (2) forgave the \$333,333 remaining on the promissory note. Neither Navidea nor R-NAV has any further obligations of any kind to either party. See Note 10.

IPFS Corporation

In December 2016, we prepaid \$348,000 of insurance premiums through the issuance of a note payable to IPFS Corporation (“IPFS”) with an interest rate of 8.99%. The note is payable in eight monthly installments of \$45,000, with the final payment due on July 10, 2017. The note is included in notes payable, current in the December 31, 2016 consolidated balance sheet.

Summary

During the years ended December 31, 2016, 2015 and 2014, we recorded interest expense of \$14.9 million, \$6.9 million and \$3.7 million, respectively, related to our notes payable. Of those amounts, \$2.0 million, \$493,000 and \$844,000, respectively, was non-cash in nature related to amortization of the debt discounts and deferred financing costs related to our notes payable. An additional \$1.6 million and \$2.0 million, respectively, of this interest expense was compounded and added to the balance of our notes payable during the years ended December 31, 2016 and 2015.

Annual principal maturities of our notes payable are \$52.0 million, \$0, \$0, \$0, \$9.5 million and \$0 in 2017, 2018, 2019, 2020, 2021 and thereafter, respectively.

13. Commitments and Contingencies

We are subject to legal proceedings and claims that arise in the ordinary course of business.

Section 16(b) Action

On August 12, 2015, a Navidea shareholder filed an action in the United States District Court for the Southern District of New York against two funds managed by Platinum alleging violations of Section 16(b) of the Securities Exchange Act of 1934, as amended, in connection with purchases and sales of the Company’s common stock by the Platinum funds, and seeking disgorgement of the short-swing profits realized by the funds (the “Litigation”). The Company was named as a nominal defendant in the Litigation.

The Litigation was resolved on the terms set forth in a settlement agreement (the “Settlement Agreement”). The Settlement Agreement was subject to a pending joint motion for approval. The Court approved the settlement on Friday, July 1, 2016. In accordance with the terms of the Settlement Agreement, the interest rate on the Platinum credit facility was reduced by 6% to 8.125% effective July 1, 2016. In addition, Platinum assumed the obligation to pay the legal costs associated with the Litigation.

Sinotau Litigation – NAV4694

On August 31, 2015, Hainan Sinotau Pharmaceutical Co., Ltd. (“Sinotau”) filed a suit for damages, specific performance, and injunctive relief against the Company in the United States District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company’s NAV4694 product candidate and technology. The Company believed the suit was without merit and filed a motion to dismiss the action. In September 2016, the Court denied the motion to dismiss. The Company filed its answer to the complaint and the case is currently in the discovery phase. At this time it is not possible to determine with any degree of certainty the ultimate outcome of this legal proceeding, including making a determination of liability. The Company intends to vigorously defend the case.

In July 2016, the Company executed a term sheet with Cerveau Technologies, Inc. (“Cerveau”) as a designated party for the rights resulting from the relationship between Navidea and Sinotau. The term sheet outlined the terms of a potential agreement between the parties to sublicense NAV4694 to Cerveau in return for license fees, milestone payments and royalties. With the exception of certain provisions, the term sheet was non-binding and was subject to the agreement of AstraZeneca, from whom the Company has licensed the NAV4694 technology. The Company had 60 days to execute a definitive agreement, however no definitive agreement was reached. Discussions related to the potential licensure or divestiture of NAV4694 are ongoing.

CRG Litigation

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company’s primary bank accounts and took possession of \$4.1 million that was on deposit, applying \$3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining \$189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million and no more than \$66 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7 million letter of credit in favor of CRG (at the Company’s cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414’s indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG’s letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The Company and CRG also agreed that the \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case would be released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7 million letter of credit, and on March 7, 2017, CRG posted a \$12 million letter of credit, each as required by the Global Settlement Agreement. The Texas hearing is currently set for July 3, 2017. See Notes 3, 12 and 24(b).

Former CEO Arbitration

On May 12, 2016 the Company received a demand for arbitration through the American Arbitration Association, Columbus, Ohio, from Ricardo J. Gonzalez, the Company's then Chief Executive Officer, claiming that he was terminated without cause and, alternatively, that he resigned in accordance with Section 4G of his Employment Agreement pursuant to a notice received by the Company on May 9, 2016. On May 13, 2016, the Company notified Mr. Gonzalez that his failure to undertake responsibilities assigned to him by the Board of Directors and otherwise work after being ordered to do so on multiple occasions constituted an effective resignation, and the Company accepted that resignation. The Company rejected the resignation of Mr. Gonzalez pursuant to Section 4G of his Employment Agreement. Also, the Company notified Mr. Gonzalez that, alternatively, his failure to return to work after the expiration of the cure period provided in his Employment Agreement constituted cause for his termination under his Employment Agreement. Mr. Gonzalez is seeking severance and other amounts claimed to be owed to him under his Employment Agreement. In addition, the Company filed counterclaims against Mr. Gonzalez alleging malfeasance by Mr. Gonzalez in his role as Chief Executive Officer. Mr. Gonzalez has withdrawn his claim for additional severance pursuant to Section 4G of his Employment Agreement, and the Company has withdrawn its counterclaims. Mr. Gonzalez has made settlement demands but the Company has made no counteroffers to date. A three-person arbitration board has been chosen and a hearing is set for April 3-7, 2017 in Columbus, Ohio.

Former Director Litigation

On August 12, 2016, the Company commenced an action in the Superior Court of California for damages and injunctive relief against former Navidea Chairman and MT Board Member Anton Gueth. The Complaint alleges, in part, that Mr. Gueth intentionally failed to disclose his prior existing relationship with CRG, in addition to multiple breaches including duty, loyalty and contract, interference and misappropriation. The litigation was dismissed without prejudice on December 19, 2016.

FTI Consulting, Inc. Litigation

On October 11, 2016, FTI Consulting, Inc. ("FTI") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in excess of \$782,600 comprised of: (i) \$730,264 for investigative and consulting services FTI alleges to have provided to the Company pursuant to an Engagement Agreement, and (ii) in excess of \$52,337 for purported interest due on unpaid invoices, plus attorneys' fees, costs and expenses. On November 14, 2016, the Company filed an Answer and Counterclaim denying the allegations of the Complaint and seeking damages on its Counterclaim, in an amount to be determined at trial, for intentional overbilling by FTI. On February 7, 2017, a preliminary conference was held by the Court at which time a scheduling order governing discovery was issued. The Court set August 31, 2017 as the deadline for FTI to file a Note of Issue and Certificate of Readiness for trial. Discovery will commence within the next few weeks. The Company intends to vigorously defend the action.

Sinotau Litigation – Tc 99m Tilmanocept

On February 1, 2017, Navidea filed suit against Sinotau in the U.S. District Court for the Southern District of Ohio. The Company's complaint included claims seeking a declaration of the rights and obligations of the parties to an agreement regarding rights for the Tc 99m tilmanocept product in China and other claims. The complaint sought a temporary restraining order ("TRO") and preliminary injunction to prevent Sinotau from interfering with the Company's Asset Sale to Cardinal Health 414. On February 3, 2017, the Court granted the TRO and extended it until March 6, 2017. The Asset Sale closed on March 3, 2017. On March 6, the Court dissolved the TRO as moot. The Ohio case remains open because all issues raised in the complaint have not been resolved.

Sinotau also filed a suit against the Company and Cardinal Health 414 in the U.S. District Court for the District of Delaware on February 2, 2017. On February 18, 2017, the Company and Cardinal Health 414 moved to stay the case pending the outcome of the Ohio case. The Court granted the motion on March 1, 2017, and the stay remains in effect.

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.

14. Preferred Stock

As discussed in Note 12, 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.

During 2013, Platinum converted 1,737.9 shares of the Series B Preferred Stock into 5,682,933 shares of our common stock under the terms of the Series B Preferred Stock. During 2014, Platinum converted 4,422 shares of the Series B Preferred Stock into 14,459,940 shares of our common stock under the terms of the Series B Preferred Stock. In November 2014, we entered into a second Securities Exchange Agreement with Platinum, pursuant to which Platinum exchanged 4,499,520 shares of our common stock owned by Platinum for 1,376 shares of our Series B Preferred Stock.

In August 2015, we entered into a Securities Exchange Agreement with two investment funds managed by Platinum to exchange the 4,519 shares of Series B Preferred Stock held by them for twenty-year warrants to purchase common stock of the Company (the “Series LL Warrants”). The Series B Preferred Stock was convertible into common stock at a conversion rate of 3,270 shares of common stock per share of Series B Preferred Stock resulting in an aggregate number of shares of common stock into which the Series B Preferred Stock was convertible of 14,777,130 shares. The exercise price of the Series LL Warrants is \$0.01 per share, and the total number of shares of common stock for which the Series LL Warrants are exercisable is 14,777,130 shares. The Series LL Warrants contain cashless exercise provisions, and the other economic terms are comparable to those of the Series B Preferred Stock, except that there is no liquidation preference associated with the Series LL Warrants or shares issuable on the exercise thereof. The Securities Exchange Agreement also contains certain provisions that prohibit the payment of dividends, distributions of common stock or issuances of common stock at effective prices less than \$1.35. There was no other consideration paid or received for the exchange. No gain or loss was recognized in our consolidated financial statements as a result of the exchange. The exchange transaction was entered into in connection with the filing of an application to list the Company’s common stock on the Tel Aviv Stock Exchange (“TASE”) in order to comply with a listing requirement of the TASE requiring that listed companies have only one class of equity securities issued and outstanding. Following the exchange, the Company has no shares of preferred stock outstanding.

15. Equity Instruments

- a. **Stock Warrants:** At December 31, 2016, there are 11.3 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from \$0.01 to \$3.04 per share with a weighted average exercise price per share of \$0.33. See Note 24(d).

The following table summarizes information about our outstanding warrants at December 31, 2016:

	<u>Exercise Price</u>	<u>Number of Warrants</u>	<u>Expiration Date</u>
Series BB	\$ 2.00	300,000	July 2018
Series HH	2.49	301,205	June 2023
Series II	3.04	275,000	June 2018
Series KK	1.918	391,032	March 2021
Series LL	0.01	9,777,130	August 2035
Series MM	2.50	150,000	September 2019
Series MM	2.50	150,000	October 2019
	<u>\$ 0.33*</u>	<u>11,344,367</u>	

* Weighted average exercise price.

In addition, at December 31, 2016, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at \$2,000 per share.

In March 2014, in connection with the Oxford Loan Agreement, the Company issued 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.

In November 2014, an outside investor exchanged their Series JJ warrants for 3,843,223 shares of our common stock in accordance with the terms of the Series JJ warrant agreement. As a result of the exchange of the Series JJ warrants, we reclassified \$7.7 million in derivative liabilities related to those warrants to additional paid-in capital.

In July 2015, we extended the expiration date of our outstanding Series BB warrants by three years to July 2018. The modification of the Series BB warrant expiry resulted in recording a non-cash selling, general and administrative expense of approximately \$150,000 during the third quarter of 2015.

In September 2015, we issued four-year Series MM warrants to purchase 150,000 shares of our common stock at an exercise price of \$2.50 per share pursuant to an advisory services agreement with Chardan Capital Markets, LLC (“Chardan”). In October 2015, we issued additional four-year Series MM warrants to purchase 150,000 shares of our common stock at an exercise price of \$2.50 per share pursuant to the advisory services agreement with Chardan. The fair value of the warrants issued to Chardan of \$256,000 was recorded as a non-cash selling, general and administrative expense during the third quarter of 2015.

In October 2015, 5,000,000 Series LL Warrants were exercised on a cashless basis in exchange for the issuance of 4,977,679 shares of our common stock.

- c. **Common Stock Reserved:** As of December 31, 2016, we have reserved 18,641,776 shares of authorized common stock for the exercise of all outstanding stock options and warrants, and upon the conversion of convertible debt and convertible preferred stock.

16. Reductions in Force

In May 2014, the Company's Board of Directors made the decision to refocus the Company's resources to better align the funding of our pipeline programs with the expected growth in Tc 99m tilmanocept revenue. As a part of the realignment, the Company terminated a total of 11 employees, including the Chief Executive Officer, Dr. Mark J. Pykett.

Effective May 30, 2014, the Company and Dr. Pykett entered into a Separation Agreement and Release. Following the termination date, Dr. Pykett was entitled to receive a \$750,000 severance payment, payable in two equal installments on June 9, 2014, and January 2, 2015, respectively; a single payment for accrued vacation and personal days; and reimbursement for certain other expenses and fees. Certain of Dr. Pykett's equity awards terminated upon separation, while others were modified in conjunction with the Separation Agreement and the Consulting Agreement described below.

Effective June 1, 2014, the Company and Dr. Pykett entered into a Consulting Agreement pursuant to which Dr. Pykett was to serve as an independent consultant to the Company until December 31, 2014 with respect to clinical-regulatory activities, commercial activities, program management, and business development, among other services. Dr. Pykett was entitled to a consulting fee of \$27,500 per month plus reimbursement of reasonable expenses. The Consulting Agreement also provided for a grant of 40,000 shares of restricted stock which were to vest upon certain service and performance conditions.

Dr. Pykett terminated the Consulting Agreement effective September 8, 2014. Certain of Dr. Pykett's equity awards were forfeited upon termination of the Consulting Agreement, while others vested on December 1, 2014 due to achievement of certain goals during the period of the Consulting Agreement, in accordance with the terms of the award agreements. The Company recognized expenses of \$94,000 under the Consulting Agreement during the year ended December 31, 2014.

During the year ended December 31, 2014, the Company recognized approximately \$557,000 of net expense as a result of the reduction in force, which included separation costs, incremental expense related to the modification of certain equity awards, and the reversal of stock compensation expense for certain equity awards for which the requisite service was not rendered.

The Company appointed Michael M. Goldberg, M.D., as interim Chief Executive Officer effective May 30, 2014. Dr. Goldberg then served as a member of the Board of Directors of the Company and did not receive any salary for his service as interim Chief Executive Officer, although the Company agreed to pay Montaur Capital Partners, LLC ("Montaur"), where Dr. Goldberg was principal, \$15,000 per month to cover additional costs and resources Montaur expected to incur or redirect due to the unavailability of Dr. Goldberg's services resulting from his service as interim Chief Executive Officer of Navidea. During the year ended December 31, 2014, the Company paid Montaur a total of \$53,000. Dr. Goldberg's service as interim Chief Executive Officer terminated with the appointment of Ricardo J. Gonzalez as the Company's Chief Executive Officer effective October 13, 2014.

In March 2015, the Company initiated a second reduction in force that included seven staff members and three executives. The executives continued as employees during transition periods of varying lengths, depending upon the nature and extent of responsibilities transitioned or wound down.

During the year ended December 31, 2015, the Company recognized approximately \$1.3 million of net expense as a result of the reduction in force, which included actual and estimated separation costs as well as the impact of accelerated vesting or forfeiture of certain equity awards resulting from the separation of \$273,000.

The remaining accrued separation costs of \$0 and \$9,000 at December 31, 2016 and 2015, respectively, related to the Company's reductions in force represent the estimated cost of continuing healthcare coverage and separation payments, and are included in accrued liabilities and other on the consolidated balance sheets.

17. Income Taxes

As of December 31, 2016 and 2015, our deferred tax assets were approximately \$79.1 million and \$74.2 million, respectively. The components of our deferred tax assets are summarized as follows:

	<u>As of December 31,</u>	
	<u>2016</u>	<u>2015</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 66,150,646	\$ 60,129,827
R&D credit carryforwards	9,729,673	9,465,900
Stock compensation	1,368,458	1,898,394
Intangibles	1,720,761	1,921,934
Temporary differences	132,475	801,002
Deferred tax assets before valuation allowance	<u>79,102,014</u>	<u>74,217,057</u>
Valuation allowance	<u>(79,102,014)</u>	<u>(74,217,057)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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, 2016 and 2015.

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, 2016.

As of December 31, 2016 and 2015, we had U.S. net operating loss carryforwards of approximately \$193.3 million and \$177.6 million, respectively. Of those amounts, \$15.3 million relates to stock-based compensation tax deductions in excess of book compensation expense ("APIC NOLs") as of both December 31, 2016 and 2015, 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.

As of December 31, 2016 and 2015, we also had state net operating loss carryforwards of approximately \$28.2 million and \$24.7 million, respectively. The state net operating loss carryforwards will begin expiring in 2032.

At December 31, 2016 and 2015, we had U.S. R&D credit carryforwards of approximately \$9.4 million and \$9.1 million, respectively.

There were no expirations of U.S. net operating loss carryforwards or R&D credit carryforwards during 2016 or 2015. The details of our U.S. net operating loss and federal R&D credit carryforward amounts and expiration dates are summarized as follows:

Generated	Expiration	As of December 31, 2016	
		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	2,999,083	218,332
2006	2026	3,049,735	365,541
2007	2027	2,842,078	342,898
2008	2028	2,777,503	531,539
2009	2029	13,727,950	596,843
2010	2030	5,397,680	1,094,449
2011	2031	1,875,665	1,950,744
2012	2032	28,406,659	468,008
2013	2033	37,450,522	681,772
2014	2034	34,088,874	816,116
2015	2035	25,073,846	492,732
2016	2036	15,581,209	358,404
Total carryforwards		<u>\$ 93,270,891</u>	<u>\$ 9,363,081</u>

The credit for certain research and experimentation expenses expired at the end of 2014. The Protecting Americans From Tax Hikes Act of 2015 (the “Act”) was signed into law by President Obama on December 18, 2015. The Act extends the credit permanently.

During the years ended December 31, 2016, 2015 and 2014, CardioSonix recorded losses for financial reporting purposes of \$13,000, \$11,000 and \$15,000, respectively. As of December 31, 2016 and 2015, CardioSonix had tax loss carryforwards in Israel of approximately \$7.7 million and \$7.6 million, respectively. 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 and the Company’s intent to dissolve CardioSonix in the near term, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2016 and 2015.

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. The Company previously completed a Section 382 analysis in 2013 and does not believe a Section 382 ownership change has occurred since then 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,					
	2016		2015		2014	
	Amount	%	Amount	%	Amount	%
Benefit at statutory rate	\$4,864,851	(34.0)%	\$9,777,786	(34.0)%	\$12,147,068	(34.0)%
Adjustments to valuation allowance	4,838,082	33.8%	9,728,667	33.8%	12,925,380	36.2%
Adjustments to R&D credit carryforwards	(239,049)	(1.6)%	(612,087)	(2.1)%	(340,886)	(1.0)%
Disqualified debt interest	188,060	1.3%	438,007	1.5%	—	0.0%
Permanent items and other	77,758	0.5%	(212,852)	(0.7)%	(437,426)	(1.2)%
Benefit per financial statements	<u>\$ —</u>		<u>\$ (436,051)</u>		<u>\$ —</u>	

18. Segments

We report information about our operating segments using the “management approach” in accordance with current accounting standards. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. Prior to 2015, our products and development programs were all related to diagnostic substances. Our majority-owned subsidiary, Macrophage Therapeutics, Inc., was formed and received initial funding during the first quarter of 2015, which resulted in a re-evaluation of the Company's segment determination. We now manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc 99m tilmanocept and other diagnostic applications of our Manocept platform, our R-NAV joint venture (terminated on May 31, 2016), NAV4694 and NAV5001 (license terminated in April 2015), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by Macrophage Therapeutics, Inc.

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

Year Ended December 31, 2016	<u>Diagnostics</u>	<u>Therapeutics</u>	<u>Corporate</u>	<u>Total</u>
Lymphoseek sales revenue:				
United States ^(a)	\$ 16,982,234	\$ —	\$ —	\$ 16,982,234
International	54,864	—	—	54,864
Lymphoseek license revenue	1,795,625	—	—	1,795,625
Grant and other revenue	3,012,217	124,766	—	3,136,983
Total revenue	<u>21,844,940</u>	<u>124,766</u>	<u>—</u>	<u>21,969,706</u>
Cost of goods sold, excluding depreciation and amortization	2,192,902	—	—	2,192,902
Research and development expenses, excluding depreciation and amortization	8,120,425	762,151	—	8,882,576
Selling, general and administrative expenses, excluding depreciation and amortization ^(b)	3,652,154	63,158	8,901,022	12,616,334
Depreciation and amortization ^(c)	104,138	—	397,231	501,369
Income (loss) from operations ^(d)	7,775,321	(700,543)	(9,298,253)	(2,223,475)
Other income (expense), excluding equity in the loss of R-NAV, LLC ^(e)	—	—	(12,070,397)	(12,070,397)
Equity in the loss of R-NAV, LLC	—	—	(15,159)	(15,159)
Net income (loss)	7,775,321	(700,543)	(21,383,809)	(14,309,031)
Total assets, net of depreciation and amortization:				
United States	\$ 3,610,354	\$ 15,075	\$ 8,703,714	\$ 12,329,143
International	131,752	—	781	132,533
Capital expenditures	—	—	1,847	1,847

Year Ended December 31, 2015	<u>Diagnostics</u>	<u>Therapeutics</u>	<u>Corporate</u>	<u>Total</u>
Lymphoseek sales revenue:				
United States ^(a)	\$ 10,229,659	\$ —	\$ —	\$ 10,229,659
International	24,693	—	—	24,693
Lymphoseek license revenue	1,133,333	—	—	1,133,333
Grant and other revenue	1,861,622	—	—	1,861,622
Total revenue	<u>13,249,307</u>	<u>—</u>	<u>—</u>	<u>13,249,307</u>
Cost of goods sold, excluding depreciation and amortization	1,654,800	—	—	1,654,800
Research and development expenses, excluding depreciation and amortization	12,046,221	730,895	—	12,777,116
Selling, general and administrative expenses, excluding depreciation and amortization ^(b)	5,852,214	123,884	10,820,392	16,796,490
Depreciation and amortization ^(c)	281,314	—	290,105	571,419
Loss from operations ^(d)	(6,585,242)	(854,779)	(11,110,497)	(18,550,518)
Other income (expense), excluding equity in the loss of R-NAV, LLC ^(e)	—	—	(9,902,424)	(9,902,424)
Equity in the loss of R-NAV, LLC	—	—	(305,253)	(305,253)
Benefit from income taxes	—	—	436,051	436,051
Net loss from continuing operations	(6,585,242)	(854,779)	(20,882,123)	(28,322,144)
Income from discontinued operations, net of tax effect ^(f)	—	—	758,609	758,609
Net loss	(6,585,242)	(854,779)	(20,123,514)	(27,563,535)
Total assets, net of depreciation and amortization:				
United States	\$ 3,948,971	\$ —	\$ 10,603,863	\$ 14,552,834
International	410,666	—	1,013	411,679
Capital expenditures	26,589	—	12,412	39,001

(a) All sales to Cardinal Health 414 are made in the United States; Cardinal Health 414 distributes the product throughout the U.S. through its network of nuclear pharmacies.

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

(c) Depreciation and amortization is reflected in cost of goods sold (\$104,138 and \$99,963 for the years ended December 31, 2016 and 2015, respectively), research and development (\$0 and \$10,617 for the years ended December 31, 2016 and 2015, respectively), and selling, general and administrative expenses (\$397,231 and \$460,839 for the years ended December 31, 2016 and 2015, respectively).

(d) Loss from operations does not reflect the allocation of certain selling, general and administrative expenses, excluding depreciation and amortization, to our individual reportable segments.

(e) Amounts consist primarily of interest income, interest expense, changes in fair value of financial instruments, and losses on debt extinguishment, which are not currently allocated to our individual reportable segments.

(f) Amount of contingent consideration recognized related to 2015 GDS Business revenue royalties pursuant to the 2011 sale of the GDS Business to Devicor, net of tax effect. See Note 1(a).

19. 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 Tc 99m tilmanocept 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 had the right to terminate the agreement upon mutual written agreement, or upon material breach by the other party if not cured within 60 days from the date of written notice of the breach. Total purchases under the manufacture and supply agreement were \$1.1 million, \$225,000 and \$300,000 for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had issued a purchase order under the manufacture and supply agreement with Reliable for \$525,000 of Tc 99m tilmanocept drug substance for delivery during 2017. Upon closing of the Asset Sale to Cardinal Health 414, our contract and open purchase order with Reliable were transferred to Cardinal Health 414.

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 expired in May 2016. In August 2014, in connection with the Company's decision to refocus its resources, the Nordion agreement was amended to provide for a suspension period during which the Company was to pay a monthly fee to maintain production space at Nordion's facility until such time as manufacture resumed. In March 2016, the Nordion agreement was terminated. Total purchases under the clinical supply agreement were \$43,000, \$244,000 and \$505,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

In August 2013, we entered into a manufacturing services agreement with PETNET Solutions, Inc. (PETNET) for the manufacture and distribution of NAV4694. The initial three-year term of the agreement expired in August 2016 and the agreement was not renewed. Total purchases under the manufacturing agreement were \$826,000, \$855,000 and \$2.2 million for the years ended December 31, 2016, 2015 and 2014, respectively.

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 Tc 99m tilmanocept. Either party had the right to terminate the agreement upon mutual written agreement, or upon material breach by the other party if not cured within 60 days from the date of written notice of the breach. During the term of agreement, OsoBio was the primary supplier of manufacturing services for Tc 99m tilmanocept. In consideration for these services, the Company paid a unit pricing fee. In addition, the Company also paid OsoBio a fee for regulatory and other support services. Total purchases under the manufacturing services agreement were \$1.2 million, \$472,000 and \$96,000 for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had issued purchase orders under the agreement with OsoBio for \$562,000 of our products for delivery during 2017. Upon closing of the Asset Sale to Cardinal Health 414, our contract and open purchase orders with OsoBio were transferred to Cardinal Health 414.

Also in September 2013, we completed a service and supply master agreement with Gipharma S.r.l. (Gipharma) for process development, manufacturing and packaging of reduced-mass vials to be sold in the EU. The agreement has an initial term of three years and automatically renews for an additional one-year periods unless written notice is provided at least six months prior to the expiration of the current term. Navidea may terminate the agreement for any reason by providing 60 days prior written notice. Either party may terminate the agreement upon material breach if not cured within 30 days from the date of written notice of the breach, or upon written notice following the other party's dissolution or cessation of normal business. In consideration for these services, the Company will pay fees as defined in the agreement. Total purchases under the service and supply master agreement were \$149,000, \$677,000 and \$272,000 for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had issued purchase orders under the agreement with Gipharma for \$1,500 of services for delivery during 2017. Following the transfer of the Tc 99m tilmanocept Marketing Authorization to SpePharm, our contract with Gipharma will be transferred to SpePharm.

- b. Research and Development Agreements:** In January 2002, we completed a license agreement with the University of California, San Diego (UCSD) for the exclusive world-wide rights to Tc 99m tilmanocept. The license agreement was effective until the later of the expiration date of the longest-lived underlying patent. In July 2014, we amended the license agreement to extend the agreement until the third anniversary of the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD 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 could 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 make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a \$25,000 minimum annual royalty. In addition, we agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets. Total costs related to the UCSD license agreement for Tc 99m tilmanocept were \$955,000, \$777,000 and \$353,000 in 2016, 2015 and 2014, respectively. Royalties on net sales of Tc 99m tilmanocept were recorded in cost of goods sold, license maintenance fees and patent-related costs were recorded in research and development expenses, and sublicense fees were recorded in selling, general and administrative expenses.

In connection with the March 2017 closing of the Asset Sale to Cardinal Health 414, the Company amended and restated its Tc 99m tilmanocept license agreement with UCSD pursuant to which UCSD granted a license to the Company to exploit certain intellectual property rights owned by UCSD and, separately, Cardinal Health 414 entered into a license agreement with UCSD pursuant to which UCSD granted a license to Cardinal Health 414 to exploit certain intellectual property rights owned by UCSD for Cardinal Health 414 to sell the Product in the Territory. Pursuant to the Purchase Agreement, the Company granted to UCSD a five (5)-year warrant to purchase up to 1 million shares of the Company's common stock, par value \$.001 per share, at an exercise price of \$1.50 per share. See Note 24(a).

In April 2008, we completed a second license agreement with UCSD for an expanded field of use allowing Tc 99m tilmanocept to be developed as an optical or ultrasound agent. The license agreement was effective until the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD 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 could 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 make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a \$25,000 minimum annual royalty. In addition, we agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets. Total costs related to the UCSD license agreement for the use of Tc 99m tilmanocept as an optical or ultrasound agent were \$25,000 in 2014, and were recorded in research and development expenses. The license agreement for the use of Tc 99m tilmanocept as an optical or ultrasound agent was canceled in July 2014.

In July 2014, the Company replaced the license agreement for the use of Tc 99m tilmanocept as an optical or ultrasound agent with an expanded license agreement for the exclusive world-wide rights to all diagnostic and therapeutic uses of tilmanocept (other than Tc 99m tilmanocept). The license agreement is effective until the third anniversary of 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 make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a \$25,000 minimum annual royalty. In addition, we agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets. Total costs related to the UCSD license agreement for tilmanocept were \$199,000, \$152,000 and \$25,000 in 2016, 2015 and 2014, respectively, and were recorded in research and development expenses.

In December 2011, we executed a license agreement with AstraZeneca AB for NAV4694, a proprietary compound that is primarily intended for use in diagnosing Alzheimer's disease and other CNS 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 \$116,000, \$80,000 and \$81,000 in 2016, 2015 and 2014, 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 provided for contingent milestone payments of up to \$2.9 million, \$2.5 million of which would have principally occurred 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 would have been issuable at the time of product registration or upon commercial sales. In addition, the sublicense terms anticipated royalties on annual net sales of the approved product which were consistent with industry-standard terms and certain sublicense extension fees, payable in cash and shares of common stock, in the event certain diligence milestones were not met. In April 2015, the Company entered into an agreement with Alseres to terminate the Alseres sublicense agreement. Under the terms of this agreement, Navidea transferred all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres agreed to reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, Navidea has supplied clinical support services for NAV5001 on a cost-plus reimbursement basis. However, to this point, Alseres has been unsuccessful in raising the funds necessary to restart the program and reimburse Navidea. As a result, we have taken steps to end our obligations under the agreement and notified Alseres that we consider them in breach of the agreement. We are in the process of trying to recover the funds we expended complying with our obligations under the termination agreement. Total costs related to the Alseres sublicense agreement were \$5,000 and \$42,000 in 2015 and 2014, respectively, and were recorded in research and development expenses.

- c. Employment Agreements:** As of December 31, 2016, we had employment agreements with two of our senior officers. In addition, although certain employment agreements expired on or before December 31, 2016, the terms of the agreements provide for continuation of certain terms of the employment agreements as long as the senior officers continue to be employees of the Company following expiration of the agreements. The employment agreements contain termination and/or change in control provisions that would entitle each of the officers to 1.3 to 2.75 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, 2016, our maximum contingent liability under these agreements in such an event is approximately \$1.9 million. The employment agreements generally also provide for severance, disability and death benefits.
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20. Leases

We lease office space in Ohio under an operating lease that expires in October 2022. Beginning in March 2017, we also lease office space in New Jersey under an operating lease that expires in March 2018.

As of December 31, 2016, the future minimum lease payments for the years ending December 31 are as follows:

	Operating Leases
2017	\$ 277,946
2018	284,246
2019	290,734
2020	297,405
2021	304,201
Thereafter	253,339
	<u>\$ 1,707,871</u>

Total rental expense was \$187,000, \$217,000 and \$357,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

21. 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 \$101,000, \$124,000 and \$125,000 during 2016, 2015 and 2014, respectively.

22. Supplemental Disclosure for Statements of Cash Flows

During 2016, 2015 and 2014, we paid interest aggregating \$5.5 million, \$4.6 million and \$2.9 million, respectively. Interest paid during 2016 included collection fees of \$778,000 and a prepayment premium of \$2.1 million, both of which were withdrawn by CRG from a bank account under their control. During 2016, 2015, and 2014, we issued 67,002, 68,157 and 36,455 shares of our common stock, respectively, as matching contributions to our 401(k) Plan which were valued at \$121,000, \$117,000 and \$100,000, respectively. In December 2016, we prepaid \$348,000 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 8.99%. During 2015 and 2014, we recorded \$1.0 million and \$2.4 million, respectively, of end-of-term fees associated with our notes payable to CRG and Oxford.

In connection with their initial investment in March 2015, the investors in MT were issued warrants that have been determined to be derivative liabilities with an estimated fair value of \$63,000. A \$46,000 deemed dividend related to the beneficial conversion feature within the MT Preferred Stock was also recorded at the time of the initial investment in MT. See Note 9.

During 2014, in connection with the Oxford Loan Agreement, we issued warrants with an estimated relative fair value of \$465,000. Also during 2014, in connection with entering into the R-NAV joint enterprise, Navidea executed a promissory note in the principal amount of \$666,666, payable in two equal installments on July 15, 2015 and July 15, 2016, the first and second anniversaries of the R-NAV transaction. See Note 10.

23. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for fiscal 2016 and 2015 are presented in the following table, in thousands, except per share data:

	For the Quarter Ending			
	March 31	June 30	September 30	December 31
2016:				
Lymphoseek sales revenue	\$ 3,783	\$ 4,232	\$ 6,690	\$ 2,332
Lymphoseek license revenue	254	246	1,296	—
Grant and other revenue	686	917	511	1,023
Gross profit	4,188	4,834	7,575	3,076
Operating expenses	6,756	5,414	4,217	5,509
Operating income (loss)	(2,568)	(580)	3,358	(2,433)
Net loss attributable to common stockholders	(3,686)	(6,681)	(59)	(3,883)
Basic and diluted net loss per share ⁽¹⁾	\$ (0.02)	\$ (0.04)	\$ (0.00)	\$ (0.03)
2015:				
Lymphoseek sales revenue	\$ 1,835	\$ 1,964	\$ 2,953	\$ 3,503
Lymphoseek license revenue	83	250	550	250
Grant and other revenue	190	654	477	541
Gross profit	1,659	2,535	3,522	3,778
Operating expenses	9,475	6,346	7,845	6,379
Operating loss	(7,816)	(3,811)	(4,323)	(2,601)
Net loss attributable to common stockholders	(7,337)	(9,691)	(8,071)	(2,510)
Basic and diluted net loss per share ⁽¹⁾	\$ (0.05)	\$ (0.06)	\$ (0.05)	\$ (0.02)

(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.

24. Subsequent Events:

- a. **Closing on the Asset Sale to Cardinal Health 414:** On March 3, 2017, pursuant to the Asset Purchase Agreement dated as of November 23, 2016 between the Company and Cardinal Health 414 (the "Purchase Agreement"), the Company completed its previously announced sale to Cardinal Health 414 of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer (the "Business"), including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the FDA and similar indications approved by the FDA in the future (the "Product"), in Canada, Mexico and the United States (the "Territory") (giving effect to the License-Back described below and excluding certain assets specifically retained by the Company) (the "Asset Sale"). Such assets sold in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all right, title and interest in and to the Product, as specified in the Purchase Agreement (the "Acquired Assets").

In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately \$80.6 million after adjustments based on inventory being transferred and an advance of \$3 million of guaranteed earnout payments as part of the CRG settlement described below, (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG described below.

Upon closing of the Asset Sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect (other than any indemnification, payment, notification or data sharing obligations which survive the termination). At the closing of the Asset Sale, Cardinal Health 414 paid to the Company \$1.2 million, as an estimate of the accrued revenue sharing payments owed to the Company as of the closing date, net of prior payments.

In connection with the closing of the Asset Sale, the Company entered into a License-Back Agreement (the "License-Back") with Cardinal Health 414. Pursuant to the License-Back, Cardinal Health 414 granted to the Company a sublicensable (subject to conditions) and royalty-free license to use certain intellectual property rights included in the Acquired Assets (as defined below) and owned by Cardinal Health 414 as of the closing of the Asset Sale to the extent necessary for the Company to (i) on an exclusive basis, subject to certain conditions, develop, manufacture, market, sell and distribute new pharmaceutical and other products that are not Competing Products (as defined in the License-Back), and (ii) on a non-exclusive basis, develop, manufacture, market, sell and distribute the Product (as defined below) throughout the world other than in the Territory. Subject to the Company's compliance with certain restrictions in the License-Back, the License-Back also restricts Cardinal Health 414 from using the intellectual property rights included in the Acquired Assets to develop, manufacture, market, sell, or distribute any product other than the Product or other product that (a) accumulates in lymphatic tissue or tumor-draining lymph nodes for the purpose of (1) lymphatic mapping or (2) identifying the existence, location or staging of cancer in a body, or (b) provides for or facilitates any test or procedure that is reasonably substitutable for any test or procedure provided for or facilitated by the Product. Pursuant to the License-Back and subject to rights under existing agreements, Cardinal Health 414 was given a right of first offer to market, sell and/or market any new products developed from the intellectual property rights licensed by Cardinal Health 414 to the Company by the License-Back.

As part of the Asset Sale, the Company and Cardinal Health 414 also entered into ancillary agreements providing for transitional services and other arrangements. The Company amended and restated its Tc 99m tilmanocept license agreement with UCSD pursuant to which UCSD granted a license to the Company to exploit certain intellectual property rights owned by UCSD and, separately, Cardinal Health 414 entered into a license agreement with UCSD pursuant to which UCSD granted a license to Cardinal Health 414 to exploit certain intellectual property rights owned by UCSD for Cardinal Health 414 to sell the Product in the Territory.

Pursuant to the Purchase Agreement, the Company granted to each of Cardinal Health 414 and UCSD a five (5)-year warrant to purchase up to 10 million shares and 1 million shares, respectively, of the Company's common stock, par value \$.001 per share, at an exercise price of \$1.50 per share, each of which warrant is subject to anti-dilution and other customary terms and conditions.

Prior to the Asset Sale, the Company had no material relationships with Cardinal Health 414 or its affiliates except that Cardinal Health 414 was the Company's primary distributor of the Product throughout the United States pursuant to the Supply and Distribution Agreement which, as set forth above, was terminated as of the closing of the Asset Sale.

Post-closing and after paying off our outstanding indebtedness and transaction-related expenses, Navidea has approximately \$15.6 million in cash and \$3.7 million in payables, a large portion of which is tied to the 4694 program which Navidea is seeking to divest in the near term. Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern has been removed.

- b. CRG Litigation and Settlement:** On February 9, 2017, The District Court of Harris County, Texas entered an interlocutory Order declaring that the Company and its subsidiary, MT, committed one or more events of default under the CRG Loan Agreement as of May 8, 2015, and granted CRG the right to exercise its remedies provided in Section 11.01 of the CRG Loan Agreement and 4.05 of the related Security Agreement, dated as of May 8, 2015, by and among the Company, MT, as guarantor, CRG and the control agent (the "Security Agreement" and together with the CRG Loan Agreement and all other documents, instruments and agreements between the Company and CRG executed in connection therewith, the "CRG Loan Documents"). The interlocutory order did not address the issues pertaining to the Company's affirmative defenses to CRG's claims, or enter an award of any amount against the Company in connection with CRG's claims under the Loan Agreement and Security Agreement.

By letter dated February 21, 2017 (the "Letter"), CRG notified the Company that, in further exercise of its remedies under the CRG Loan Documents, including, without limitation, pursuant to Sections 4.01 through 4.13 and Section 5.04 of the Security Agreement and Sections 11.02 and 12.03 of the CRG Loan Agreement, CRG Servicing LLC, CRG's representative, would sell (or lease or license, as applicable), at a public sale, (A) the stock of MT owned by the Company and pledged to CRG pursuant to the CRG Loan Documents and (B) the U.S. Collateral (as defined in the Security Agreement) related to Tc 99m tilmanocept on March 13, 2017. CRG claimed that, as of January 31, 2017, the outstanding obligations due under the CRG Loan Documents, including outstanding principal, interest, fees, and expenses, aggregated \$63,198,774.46 (the "Asserted Payoff Amount"). CRG claimed that interest, fees and expenses would continue to accrue and CRG reserved the right to adjust or supplement the Asserted Payoff Amount prior to the date of the public sale. The Asserted Payoff Amount was also calculated by CRG to include costs incurred by CRG through January 31, 2017 in respect of indemnity obligations of the Company under Sections 12.03(a)(ii) and 12.03(b) of the CRG Loan Agreement (the "Indemnity Obligations"), which CRG claimed were secured obligations under the Security Agreement. CRG claimed that, unless and until all Indemnity Obligations (inclusive of costs incurred by CRG subsequent to January 31, 2017) are indefeasibly paid in full, in cash, as contemplated by the Security Agreement, such Indemnity Obligations would continue to be secured by the liens created by and perfected in accordance with the Security Agreement in all collateral not sold in the public sale, including any cash proceeds of the public sale in excess of the Asserted Payoff Amount, which cash proceeds would be deposited into an escrow account and would be subject to CRG's continuing lien. CRG also noted that payment of the Asserted Payoff Amount (as such amount may be adjusted or supplemented immediately prior to the public sale) would not result in the indefeasible payment in full of the Secured Obligations unless payment of the Asserted Payoff Amount, as adjusted or supplemented, was concurrently accompanied by a general release by the Company, MT, as guarantor, and the successful bidder(s) of all present and future claims

and counterclaims against CRG.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of the settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount, inclusive of the \$59 million repaid on March 3, 2017, would be no less than \$47 million and no more than \$66 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The Company and CRG also agreed that the \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case would be released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7 million letter of credit, and on March 7, 2017, CRG posted a \$12 million letter of credit, each as required by the Global Settlement Agreement. The trial date is currently set for July 3, 2017. See Note 12.

- c. **Platinum Note Payment:** In addition to payment of the Deposit Amount to CRG described above, the Company repaid to PPCO an aggregate of approximately \$7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement by and between the Company and Platinum-Montaur, which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA. See Note 12.
 - d. **Series LL Warrant Exercise:** On January 17, 2017, Dr. Goldberg exercised 5,411,850 of his Series LL warrants for gross proceeds to the Company of \$54,119. See Note 15(a).
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**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
NAVIDEA BIOPHARMACEUTICALS, INC.**

*(as corrected February 18, 1994, and as 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, June 26, 2013 and August 18, 2016)*

(Article One was amended to change the Company's legal name to "Navidea Biopharmaceuticals, Inc." pursuant to the filing on December 16, 2011, of a Certificate of Ownership in Delaware to effect a merger of the Company's wholly owned subsidiary, Neoprobe Name Change, Inc., with and into the Company on January 5, 2012, at 12:01 a.m. eastern time. Pursuant to Section 253 of the General Corporation Law of Delaware, the merger had the effect of amending the Company's Amended and Restated Certificate of Incorporation to reflect the new legal name of the Company.)

ARTICLE ONE

The name of the corporation is Navidea Biopharmaceuticals, Inc.

ARTICLE TWO

The address of the corporation's registered office in the State of Delaware is the Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle. The name of its registered agent at such address is the Corporation Trust Company.

ARTICLE THREE

The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

(Article Four was amended to increase the total number of authorized shares from 22,000,000 to 55,000,000, the total number of shares of Common Stock from 20,000,000 to 50,000,000 and the total number of shares of Preferred Stock from 2,000,000 to 5,000,000 by a resolution duly adopted by the Board of Directors on March 3, 1994 and duly adopted by the stockholders on May 26, 1994. It was again amended to increase the number of authorized shares to 80,000,000, consisting of 75,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock, by resolution duly adopted by the Board of Directors on April 15, 2003, and duly adopted by the stockholders on June 12, 2003. It was further amended to increase the number of authorized shares to 105,000,000, consisting of 100,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock, by resolution duly adopted by the Board of Directors on April 16, 2004, and duly adopted by the stockholders on July 27, 2004. Article Four was again amended to increase the number of authorized shares to 155,000,000, consisting of 150,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock, by resolution duly adopted by the Board of Directors on March 15, 2005, and duly adopted by the Stockholders on June 13, 2005, and was further amended to increase the number of authorized shares to 205,000,000, consisting of 200,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock, by resolution duly adopted by the Board of Directors on May 12, 2010, and duly adopted by the Stockholders on July 16, 2010. It was further amended to increase the number of authorized shares to 305,000,000, consisting of 300,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock by resolution duly adopted by the Board of Directors on June 14, 2016, and duly adopted by the Stockholders on August 11, 2016.)

ARTICLE FOUR

4.1 Authorized Shares. The total number of shares of capital stock which the Corporation has authority to issue is 305,000,000 shares, consisting of:

- (a) 300,000,000 shares of Common Stock, par value \$.001 per share (the "Common Stock");
- (b) 5,000,000 shares of Preferred Stock, par value \$.001 per share (the "Preferred Stock").

4.2 Common Stock.

(a) Subject to such voting rights of any other class or series of securities as may be granted from time to time pursuant to this certificate of incorporation, any amendment thereto, or the provisions of the laws of the State of Delaware governing corporations, voting rights shall be vested exclusively in the holders of Common Stock. Each holder of Common Stock shall have one vote in respect of each share of such stock held.

(b) Subject to the rights of any other class or series of stock, the holders of shares of Common Stock shall be entitled to receive, when and as declared by the board of directors, out of the assets of the Corporation legally available therefor, such dividends as may be declared from time to time by the board of directors.

(c) Subject to such rights of any other class or series of securities as may be granted from time to time, the holders of shares of

Common Stock shall be entitled to receive all the assets of the Corporation available for distribution to shareholders in the event of the voluntary or involuntary liquidation, dissolution, or winding up of the Corporation, ratably, in proportion to the number of shares of Common Stock held by them. Neither the merger or consolidation of the Corporation into or with any other corporation, nor the merger or consolidation of any other corporation into or with the Corporation, nor the sale, lease, exchange or other disposition (for cash, shares of stock, securities, or other consideration) of all or substantially all the assets of the Corporation, shall be deemed to be a dissolution, liquidation, or winding up, voluntary or involuntary, of the Corporation.

4.3 Preferred Stock. Shares of Preferred Stock may be issued from time to time in one or more series. The board of directors of the Corporation is hereby authorized to determine and alter all rights, preferences, and privileges and qualifications, limitations, and restrictions thereof (including, without limitation, voting rights and the limitation and exclusion thereof) granted to or imposed upon any wholly unissued series of Preferred Stock and the number of shares constituting any such series and the designation thereof, and to increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series subsequent to the issue of shares of that series then outstanding. In case the number of shares of any series is so decreased, the shares constituting such reduction shall resume the status which such shares had prior to the adoption of the resolution originally fixing the number of shares of such series.

ARTICLE FIVE

The business and affairs of the Corporation shall be managed by or under the direction of the board of directors, and the directors need not be elected by ballot unless required by the by-laws of the Corporation. In furtherance and not in limitation of the powers conferred by statute, the board of directors of the Corporation is expressly authorized to adopt, amend, or repeal the by-laws of the Corporation.

ARTICLE SIX

Action shall be taken by the stockholders of the Corporation only at annual or special meetings of stockholders, and stockholders may not act by written consent. Special meetings of the Corporation may be called only as provided in the by-laws.

ARTICLE SEVEN

Meetings of the stockholders may be held within or without the State of Delaware, as the by-laws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the board of directors or in the by-laws of the Corporation. The board of directors shall from time to time decide whether and to what extent and at what times and under what conditions and requirements the accounts and books of the Corporation, or any of them, except the stock book, shall be open to the inspection of the stockholders, and no stockholder shall have any right to inspect any books or documents of the Corporation except as conferred by the laws of the State of Delaware or as authorized by the board of directors.

(Article Eight was amended in its entirety by a resolution duly adopted by the Board of Directors on January 18, 1996 and duly adopted by the stockholders at the Annual Meeting of Stockholders held on May 30, 1996).

ARTICLE EIGHT

Notwithstanding any other provision set forth in the Certificate of Incorporation of the Corporation or its By-laws, the board of directors shall be divided into three classes; the term of office of those of the first class to expire at the annual meeting next ensuing; of the second class one year thereafter; of the third class two years thereafter; and at each annual election held after the initial classification of the board of directors and election of directors to such classes, directors shall be chosen for a full term of three years, as the case may be, to succeed those whose terms expire. The total number of directors constituting the full board of directors and the number of directors in each class shall be fixed by, or in the manner provided in the by-laws, but the total number of directors shall not exceed seventeen (17) nor shall the number of directors in any class exceed six (6). Subject to the foregoing, the classes of directors need not have the same number of members. No reduction in the total number of directors or in the number of directors in any class shall be effective to remove any director or to reduce the term of any director. If the board of directors increases the number of directors in a class, it may fill the vacancy created thereby for the full remaining term of a director in that class even though such term may extend beyond the next annual election. The board of directors may fill any vacancy occurring for any other reason for the full remaining term of the director whose death, resignation or removal caused the vacancy, even though such term may extend beyond the next annual election.

ARTICLE NINE

(a) The Corporation shall, to the fullest extent permitted by the General Corporation Law of the State of Delaware as the same exists or may hereafter be amended, indemnify all persons whom it may indemnify pursuant hereto.

(b) To the fullest extent permitted by the General Corporation Law of the State of Delaware as the same exists or may hereafter be amended, a director of this Corporation shall not be personally liable for the Corporation or its Stockholders for monetary damages for breach of fiduciary duty as a director. The modification or repeal of this Article Nine shall not affect the restriction hereunder of a director's personal liability for any breach, act, or omission occurring prior to such modification or repeal.

ARTICLE TEN

The Corporation is to have perpetual existence.

* * *

(A Certificate of Correction was filed to correct a failure to set forth in the Restated Certificate of Incorporation filed with the Secretary of State of Delaware on November 9, 1992, the following resolutions duly adopted by the Board and duly approved by the stockholders):

WHEREAS, the Board of Directors of the Corporation deems it to be advisable and in the best interests of the Corporation that the Corporation effectuates a reverse split of its common stock, par value \$0.001 per share (the "Common Stock"), to cause the total number of issued and outstanding shares of Common Stock to be 5,162,762 prior to a contemplated public offering of the securities of the Corporation; it is therefore:

RESOLVED, that, subject to approval by the Corporation's stockholders, there is hereby declared a one-for-two reverse split of the issued and outstanding shares of Common Stock, effective immediately prior to the effective time of the contemplated public offering (the "Conversion Time"), pursuant to which each issued and outstanding share of Common Stock shall automatically be converted into one-half of the one share of Common Stock, and each stockholder of record at the Conversion Time shall receive one or more certificates representing the number of fully-paid and nonassessable shares of Common Stock equal to the number of shares held after the Conversion Time as a result of the foregoing reverse split;

RESOLVED, FURTHER, that the shares of Common Stock that cease to be outstanding as a result of the reverse stock split shall be authorized but unissued shares;

RESOLVED, FURTHER, that fractions of a share existing after the reverse stock split shall not be issued to the stockholders, and that such fractions shall be paid in cash at their *pro rata* fair value, which the Board of Directors hereby determines, after due consideration, to be \$6.00 per share as of the Conversion Time;

RESOLVED, FURTHER, that appropriate adjustment shall be made to the applicable conversion or other ratios of the Corporation's outstanding warrants, options or other convertible securities to take account of the change in the outstanding Common Stock resulting from the reverse stock split; and

RESOLVED, FURTHER, that the Conversion Time for the one-for-two reverse split of the issued and outstanding shares of Common Stock as authorized on July 22, 1992, and approved by the Corporation's stockholders, shall be at the close of business on Monday, November 9, 1992.

* * *

(The Board of Directors provided for a series of Preferred Stock on July 18, 1995 by the addition to the Certificate of Incorporation of provisions which were incorporated in a Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock filed on July 25, 1995, which were later removed by a Certificate of Elimination filed on November 20, 2006.)

* * *

(The Board of Directors provided for a series of Preferred Stock on December 21, 2007 by the addition to the Certificate of Incorporation of the following provisions which were incorporated in a Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions and Relative Rights of Series A 8% Cumulative Convertible Preferred Stock filed on December 26, 2007, which were later amended and restated by a Certificate of Amendment filed on April 30 2009, and further amended and restated by a Certificate of Amendment filed July 27, 2009. These provisions were later removed by a Certificate of Elimination filed on August 2, 2010.)

* * *

(The Board of Directors provided for an additional series of Preferred Stock on June 18, 2010 by the addition to the Certificate of Incorporation of the following provisions which were incorporated in a Certificates of Designations, Voting Powers, Preferences, Limitations, Restrictions and Relative Rights of Series B Convertible Preferred Stock filed on June 22, 2010 and further amended and restated by a Certificate of Amendment filed on June 24, 2013.)

* * *

(The Board of Directors provided for an additional series of Preferred Stock on June 18, 2010 by the addition to the Certificate of Incorporation of the following provisions which were incorporated in a Certificates of Designations, Voting Powers, Preferences, Limitations, Restrictions and Relative Rights of Series C Convertible Preferred Stock filed on June 22, 2010. These provisions were later removed by a Certificate of Elimination filed on June 26, 2013.)

1. Designation and Rank.

(a) Designation. The designation of such series of the Preferred Stock shall be the Series B Convertible Preferred Stock, par value \$.001 per share (the "Series B Preferred Stock"). The maximum number of shares of Series B Preferred Stock shall be Twelve Thousand (12,000) Shares.

(b) Rank. The Series B Preferred Stock shall rank prior to the common stock, par value \$.001 per share (the "Common Stock"), and to all other classes and series of equity securities of the Company which by their terms do not rank on a parity with or senior to the Series B Preferred Stock ("Junior Stock"). The Series B Preferred Stock shall be subordinate to and rank junior to all indebtedness of the Company now or hereafter outstanding.

2. Dividends. Whenever the Board of Directors declares a dividend on the Common Stock, each holder of record of a share of Series B Preferred Stock, or any fraction of a share of Series B Preferred Stock, on the date set by the Board of Directors to determine the owners of the Common Stock of record entitled to receive such dividend (the "Record Date") shall be entitled to receive, out of any assets at the time

legally available therefore, an amount equal to such dividend declared on one share of Common Stock multiplied by the number of shares of Common Stock into which such share, or such fraction of a share, of Series B Preferred Stock could be converted on the Record Date, without regard to Section 7 hereof.

3. Voting Rights.

(a) **Class Voting Rights.** The Series B Preferred Stock shall have the following class voting rights. The Company shall not, without the affirmative vote or consent of the holders of at least a majority of the shares of the Series B Preferred Stock outstanding at the time, given in person or by proxy, either in writing or at a meeting, in which the holders of the Series B Preferred Stock vote separately as a class, amend, alter or repeal the provisions of the Series B Preferred Stock so as to adversely affect any right, preference, privilege or voting power of the Series B Preferred Stock. So long as at least 25% of the shares of the Series B Preferred Stock remain outstanding, the Company shall not, without the affirmative vote or consent of the holders of at least a majority of the shares of the Series B Preferred Stock outstanding at the time, given in person or by proxy, either in writing or at a meeting, in which the holders of the Series B Preferred Stock vote separately as a class: (i) repurchase, redeem or pay dividends on (whether in cash, in kind, or otherwise), shares of the Company's Junior Stock; (ii) effect any distribution with respect to any Junior Stock, or (iii) issue any Common Stock or Common Stock equivalent for a per Common Stock share effective price less than \$1.35, other than (1) issuances of securities upon the exercise or exchange of or conversion of any securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the Issuance Date, provided that such securities have not been amended since the Issuance Date to increase the number of such securities or to decrease the exercise, exchange or conversion price of any such securities; (2) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors, but not including a transaction with an entity whose primary business is investing in securities or a transaction, the primary purpose of which is to raise capital; or (3) issuances, pursuant to employee equity compensation plans approved by the Company's shareholders, of options, restricted stock or other forms of equity compensation to employees, officers or directors of the Company, approved by a majority of the non-employee members of the Board of Directors of the Company or a majority of the members of a committee of nonemployee directors established for such purpose. For purposes of clause (iii) above, the "per Common Stock share effective price" in the case of any Common Stock equivalent shall be determined by dividing (X) the total amount received or receivable by the Company as consideration for the issue or sale of such Common Stock equivalents, plus the minimum aggregate amount of additional consideration, if any, payable to the Company upon the conversion or exercise thereof, by (Y) the total maximum number of shares of Common Stock issuable upon the conversion or exercise of all such Common Stock equivalents.

(b) **General Voting Rights.** Except with respect to transactions upon which the Series B Preferred Stock shall be entitled to vote separately as a class pursuant to Section 3(a) above, the Series B Preferred Stock shall have no voting rights. The Common Stock into which the Series B Preferred Stock is convertible shall, upon issuance, have all of the same voting rights as other issued and outstanding Common Stock of the Company.

4. Liquidation Preference.

(a) In the event of the liquidation, dissolution or winding up of the affairs of the Company, whether voluntary or involuntary, after payment or provision for payment of the debts and other liabilities of the Company, the holders of shares of the Series B Preferred Stock then outstanding shall be entitled to receive, out of the assets of the Company, whether such assets are capital or surplus of any nature, before any payment shall be made or any assets distributed to the holders of the Common Stock or any other Junior Stock, an amount per share of Series B Preferred Stock calculated by taking the total amount available for distribution to holders of all the Company's outstanding Common Stock before deduction of any preference payments for the Series B Preferred Stock, divided by the total of (x) all of the then outstanding shares of the Company's Common Stock plus (y) all of the shares of the Company's Common Stock into which all of the outstanding shares of the Series B Preferred Stock can be converted, and then (z) multiplying the sum so obtained by the number of shares of Common Stock into which such share of Series B Preferred Stock could then be converted (the "Liquidation Preference Amount"). The liquidation payment with respect to each outstanding fractional share of Series B Preferred Stock shall be equal to a ratably proportionate amount of the liquidation payment with respect to each outstanding share of Series B Preferred Stock. All payments for which this Section 4(a) provides shall be in cash, property (valued at its fair market value as determined by an independent appraiser reasonably acceptable to the holders of a majority of the Series B Preferred Stock), or a combination thereof; provided, however, that no cash shall be paid to holders of Junior Stock unless each holder of the outstanding shares of Series B Preferred Stock has been paid in cash the full Liquidation Preference Amount to which such holder is entitled as provided herein. 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.

(b) A consolidation or merger of the Company with or into any other corporation or corporations, or a sale of all or substantially all of the assets of the Company, or the effectuation by the Company of a transaction or series of transactions in which more than 50% of the voting shares of the Company is disposed of or conveyed, shall be, at the election of the holders of a majority of the Series B Preferred Stock, deemed to be a liquidation, dissolution, or winding up within the meaning of this Section 4; provided, however, that any such transaction shall not be deemed to be a liquidation, dissolution or winding up unless such transaction is approved by the Board of Directors of the Company and the holders of the Series B Preferred Stock do not control the Board of Directors. In the event of the merger or consolidation of the Company with or into another corporation that is not treated as a liquidation pursuant to this Section 4(b), the Series B Preferred Stock shall maintain its relative powers, designations and preferences provided for herein (including any adjustment required under Section 5(c)(v) hereof) and no merger shall result inconsistent therewith.

(c) Written notice of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company, stating a payment date and the place where the distributable amounts shall be payable, shall be given by mail, postage prepaid, no less than forty-five (45) days prior to the payment date stated therein, to the holders of record of the Series B Preferred Stock at their respective addresses as the same shall appear on the books of the Company.

5. Conversion. The holders of Series B Preferred Stock shall have the following conversion rights (the "Conversion Rights"):

(a) **Right to Convert.** At any time on or after the date of issuance of the Series B Preferred Stock (the "Issuance Date"), the holder of any such shares of Series B Preferred Stock may, at such holder's option, subject to the limitations set forth in Section 7 herein, elect to

convert (a “Voluntary Conversion”) all or any portion of the shares of Series B Preferred Stock held by such person into a number of fully paid and nonassessable shares of Common Stock at a conversion rate of Three Thousand Two Hundred Seventy (3,270) shares of Common Stock for each share of Preferred Stock (subject to adjustments set forth in Section 5(c) herein, the “Conversion Rate”). The Company shall keep written records of the conversion of the shares of Series B Preferred Stock converted by each holder. A holder shall be required to deliver the original certificates representing the shares of Series B Preferred Stock upon any conversion of the Series B Preferred Stock as provided in Section 5(b) below.

(b) Mechanics of Voluntary Conversion. The Voluntary Conversion of Series B Preferred Stock shall be conducted in the following manner:

(i) Holder's Delivery Requirements. To convert Series B Preferred Stock into full shares of Common Stock on any date (the “Voluntary Conversion Date”), the holder thereof shall (A) transmit by facsimile (or otherwise deliver), for receipt on or prior to 5:00 p.m., Eastern Time on such date, a copy of a fully executed notice of conversion in the form attached hereto as Exhibit I (the “Conversion Notice”), to the Company, and (B) with respect to the final conversion of shares of Series B Preferred Stock held by any holder, such holder shall surrender to a common carrier for delivery to the Company as soon as practicable following such Conversion Date but in no event later than six (6) business days after such date the original certificates representing the shares of Series B Preferred Stock being converted (or an indemnification undertaking with respect to such shares in the case of their loss, theft or destruction) (the “Preferred Stock Certificates”).

(ii) Company's Response. Upon receipt by the Company of a facsimile copy of a Conversion Notice, the Company shall immediately send, via facsimile, a confirmation of receipt of such Conversion Notice to such holder and the Company or its designated transfer agent (the “Transfer Agent”), as applicable, shall, within five (5) business days following the date of receipt by the Company of the certificate representing the shares of Series B Preferred Stock being converted, (x) issue and deliver to the Depository Trust Company (“DTC”) account on the holder’s behalf via the Deposit Withdrawal Agent Commission System (“DWAC”) as specified in the Conversion Notice, registered in the name of the holder or its designee, for the number of shares of Common Stock to which the holder shall be entitled, and (y) if the certificate so surrendered represents more shares of Series B Preferred Stock than those being converted, issue and deliver to the holder a new certificate for such number of shares of Series B Preferred Stock represented by the surrendered certificate which were not converted.

(iii) Record Holder. The person or persons entitled to receive the shares of Common Stock issuable upon a conversion of the Series B Preferred Stock shall be treated for all purposes as the record holder or holders of such shares of Common Stock on the Conversion Date.

(iv) Company's Failure to Timely Convert. If within five (5) business days of the Company's receipt of the Conversion Notice (the “Share Delivery Period”) the Company shall fail to issue and deliver to a holder the number of shares of Common Stock to which such holder is entitled upon such holder's conversion of the Series B Preferred Stock (a “Conversion Failure”), in addition to all other available remedies which such holder may pursue hereunder, the Company shall pay additional damages to such holder on each business day after such fifth (5th) business day that such conversion is not timely effected in an amount equal to 0.5% of the product of (A) the sum of the number of shares of Common Stock not so issued to the holder on a timely basis pursuant to Section 5(b)(ii) and to which such holder is entitled and (B) the closing bid price of the Common Stock on the last possible date which the Company could have issued such Common Stock to such holder without violating Section 5(b)(ii). If the Company fails to pay the additional damages set forth in this Section 5(b)(iv) within five (5) business days of the date incurred, then such payment shall bear interest at the rate of 2% per month (pro rated for partial months) until such payments are made.

(c) Adjustments of Conversion Rate.

(i) Adjustments for Stock Splits and Combinations. If the Company shall at any time or from time to time after the Issuance Date, effect a stock split of the outstanding Common Stock, the Conversion Rate shall be proportionately increased. If the Company shall at any time or from time to time after the Issuance Date, combine the outstanding shares of Common Stock, the Conversion Rate shall be proportionately decreased. Any adjustments under this Section 5(c)(i) shall be effective at the close of business on the date the stock split or combination occurs.

(ii) Adjustments for Certain Dividends and Distributions. If the Company shall at any time or from time to time after the Issuance Date, make or issue or set a record date for the determination of holders of Common Stock entitled to receive a dividend or other distribution payable in shares of Common Stock, then, and in each event, the Conversion Rate shall be increased as of the time of such issuance or, in the event such record date shall have been fixed, as of the close of business on such record date, by multiplying, as applicable, the Conversion Rate then in effect by a fraction:

(A) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately following the time of such issuance or the close of business on such record date; and

(B) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance.

(iii) Adjustment for Other Dividends and Distributions. If the Company shall at any time or from time to time after the Issuance Date, make or issue or set a record date for the determination of holders of Common Stock entitled to receive a dividend or other distribution payable in securities of the Company other than shares of Common Stock, then, and in each event, an appropriate revision to the applicable Conversion Rate shall be made and provision shall be made (by adjustments of the Conversion Rate or otherwise) so that the holders of Series B Preferred Stock shall receive upon conversions thereof, in addition to the number of shares of Common Stock receivable thereon, the number of securities of the Company which they would have received had their Series B Preferred Stock been converted into Common Stock on the date of such event (without regard to Section 7 hereof) and had thereafter, during the period from the date of such event to and including the Conversion Date, retained such securities (together with any distributions payable thereon during such period), giving application to all adjustments called for during such period under this Section 5(c)(iii) with respect to the

rights of the holders of the Series B Preferred Stock.

(iv) Adjustments for Reclassification, Exchange or Substitution. If the Common Stock issuable upon conversion of the Series B Preferred Stock at any time or from time to time after the Issuance Date shall be changed to the same or different number of shares of any class or classes of stock, whether by reclassification, exchange, substitution or otherwise (other than by way of a stock split or combination of shares or stock dividends provided for in Sections 5(c)(i), (ii) and (iii), or a reorganization, merger, consolidation, or sale of assets provided for in Section 5(c)(v)), then, and in each event, an appropriate revision to the Conversion Rate shall be made and provisions shall be made so that the holder of each share of Series B Preferred Stock shall have the right thereafter to convert such share of Series B Preferred Stock into the kind and amount of shares of stock and other securities receivable upon reclassification, exchange, substitution or other change, by holders of the number of shares of Common Stock into which such share of Series B Preferred Stock might have been converted immediately prior to such reclassification, exchange, substitution or other change (without giving effect to the limitations set forth in Section 7 hereof), all subject to further adjustment as provided herein.

(v) Adjustments for Reorganization, Merger, Consolidation or Sales of Assets. If at any time or from time to time after the Issuance Date there shall be a capital reorganization of the Company (other than by way of a stock split or combination of shares or stock dividends or distributions provided for in Section 5(c)(i), (ii) and (iii), or a reclassification, exchange or substitution of shares provided for in Section 5(c)(iv)), or a merger or consolidation of the Company with or into another corporation, or the sale of all or substantially all of the Company's properties or assets to any other person that is not deemed a liquidation pursuant to Section 4(b) (an "Organic Change"), then as a part of such Organic Change an appropriate revision to the Conversion Rate shall be made and provision shall be made so that the holder of each share of Series B Preferred Stock shall have the right thereafter to convert such share of Series B Preferred Stock into the kind and amount of shares of stock and other securities or property of the Company or any successor corporation resulting from the Organic Change as the holder would have received as a result of the Organic Change and if the holder had converted its Series B Preferred Stock (without regard to Section 7 hereof) into the Company's Common Stock prior to the Organic Change.

(vi) Record Date. In case the Company shall take record of the holders of its Common Stock or any other Preferred Stock for the purpose of entitling them to subscribe for or purchase Common Stock or Convertible Securities, then the date of the issue or sale of the shares of Common Stock shall be deemed to be such record date.

(d) No Impairment. The Company shall not, by amendment of its Certificate of Incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at all times in good faith, assist in the carrying out of all the provisions of this Section 5 and in the taking of all such action as may be necessary or appropriate in order to protect the Conversion Rights of the holders of the Series B Preferred Stock against impairment. In the event a holder shall elect to convert any shares of Series B Preferred Stock as provided herein, the Company cannot refuse conversion based on any claim that such holder or anyone associated or affiliated with such holder has been engaged in any violation of law, unless an injunction from a court, on notice, restraining and/or adjoining conversion of all or of said shares of Series B Preferred Stock shall have been issued.

(e) Certificates as to Adjustments. Upon occurrence of each adjustment or readjustment of the Conversion Rate or number of shares of Common Stock issuable upon conversion of the Series B Preferred Stock pursuant to this Section 5, the Company at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of such Series B Preferred Stock a certificate setting forth such adjustment and readjustment, showing in detail the facts upon which such adjustment or readjustment is based. The Company shall, upon written request of the holder of such affected Series B Preferred Stock, at any time, furnish or cause to be furnished to such holder a like certificate setting forth such adjustments and readjustments, the Conversion Rate in effect at the time, and the number of shares of Common Stock and the amount, if any, of other securities or property which at the time would be received upon the conversion of a share of such Series B Preferred Stock. Notwithstanding the foregoing, the Company shall not be obligated to deliver a certificate unless such certificate would reflect an increase or decrease of at least one percent (1%) of such adjusted amount.

(f) Issue Taxes. The Company shall pay any and all issue and other taxes, excluding federal, state or local income taxes, that may be payable in respect of any issue or delivery of shares of Common Stock on conversion of shares of Series B Preferred Stock pursuant thereto; provided, however, that the Company shall not be obligated to pay any transfer taxes resulting from any transfer requested by any holder in connection with any such conversion.

(g) Notices. Any notice, demand, request, waiver or other communication required or permitted to be given hereunder shall be in writing and shall be effective (i) upon hand delivery, telecopy or facsimile at the address or number designated in the Exchange Agreement (if delivered on a business day during normal business hours where such notice is to be received), or the first business day following such delivery (if delivered other than on a business day during normal business hours where such notice is to be received) or (ii) on the second business day following the date of mailing by express overnight courier service, fully prepaid, addressed to such address, or upon actual receipt of such mailing, whichever shall first occur. The Company will give written notice each holder of Series B Preferred Stock at least ten (10) days prior to the date on which the Company takes a record (A) with respect to any dividend or distribution upon the Common Stock, (B) with respect to any pro rata subscription offer to holders of Common Stock or (C) for determining rights to vote with respect to any Organic Change, dissolution, liquidation or winding-up and in no event shall such notice be provided to such holder prior to such information being made known to the public. Subject to Section 4(c), the Company will also give written notice to each holder of Series B Preferred Stock at least ten (10) days prior to the date on which any Organic Change will take place and in no event shall such notice be provided to such holder prior to such information being made known to the public.

(h) Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of the Series B Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Company shall at its option either (i) pay cash equal to the product of such fraction multiplied by the average of the closing bid prices of the Common Stock for the five (5) consecutive trading days immediately preceding the Voluntary Conversion Date, as applicable, or (ii) in lieu of issuing such fractional shares issue one additional whole share to the holder.

(i) **Reservation of Common Stock.** The Company shall, so long as any shares of Series B Preferred Stock are outstanding, reserve and keep available out of its authorized and unissued Common Stock, solely for the purpose of effecting the conversion of the Series B Preferred Stock, such number of shares of Common Stock as shall from time to time be sufficient to effect the conversion of all of the Series B Preferred Stock then outstanding (without regard to the limitations on conversion set forth in Section 7 hereof).

(j) **Retirement of Series B Preferred Stock.** Conversion of Series B Preferred Stock shall be deemed to have been effected on the applicable Voluntary Conversion Date. The Company shall keep written records of the conversion of the shares of Series B Preferred Stock converted by each holder. A holder shall be required to deliver the original certificates representing the shares of Series B Preferred Stock upon complete conversion of the Series B Preferred Stock represented by such certificates. A delivery of original certificates pursuant to Section 5(b)(i) shall be deemed to comply with the requirements of this Section 5(j).

(k) **Regulatory Compliance.** If any shares of Common Stock to be reserved for the purpose of conversion of Series B Preferred Stock require registration or listing with or approval of any governmental authority, stock exchange or other regulatory body under any federal or state law or regulation or otherwise before such shares may be validly issued or delivered upon conversion, the Company shall, at its sole cost and expense, in good faith and as expeditiously as possible, endeavor to secure such registration, listing or approval, as the case may be.

6. **No Preemptive Rights.** Except as provided in Section 5 hereof, no holder of the Series B Preferred Stock shall be entitled to rights to subscribe for, purchase or receive any part of any new or additional shares of any class, whether now or hereinafter authorized, or of bonds or debentures, or other evidences of indebtedness convertible into or exchangeable for shares of any class, but all such new or additional shares of any class, or any bond, debentures or other evidences of indebtedness convertible into or exchangeable for shares, may be issued and disposed of by the Board of Directors on such terms and for such consideration (to the extent permitted by law), and to such person or persons as the Board of Directors in their absolute discretion may deem advisable.

7. **Conversion Restriction.** Notwithstanding anything to the contrary set forth in Section 5 of this Certificate of Designation, at no time may a holder of shares of Series B Preferred Stock convert shares of the Series B Preferred Stock if the number of shares of Common Stock to be issued pursuant to such conversion would exceed, when aggregated with all other shares of Common Stock owned by such holder at such time, the number of shares of Common Stock which would result in such holder owning (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules thereunder) more than 9.99% of all of the Common Stock outstanding at such time; provided, however, that upon a holder of Series B Preferred Stock providing the Company with sixty-one (61) days notice (pursuant to Section 5(g) hereof) (the "Waiver Notice") that such holder would like to waive Section 7 of this Certificate of Designation with regard to any or all shares of Common Stock issuable upon conversion of Series B Preferred Stock, this Section 7 shall be of no force or effect with regard to those shares of Series B Preferred Stock referenced in the Waiver Notice.

8. Inability to Fully Convert.

(a) **Holder's Option if Company Cannot Fully Convert.** If, upon the Company's receipt of a Conversion Notice, the Company cannot issue shares of Common Stock for any reason, including, without limitation, because the Company (i) does not have a sufficient number of shares of Common Stock authorized and available, or (ii) is otherwise prohibited by applicable law or by the rules or regulations of any stock exchange, interdealer quotation system or other self-regulatory organization with jurisdiction over the Company or its securities from issuing all of the Common Stock which is to be issued to a holder of Series B Preferred Stock pursuant to a Conversion Notice, then the Company shall issue as many shares of Common Stock as it is able to issue in accordance with such holder's Conversion Notice, and with respect to the unconverted Series B Preferred Stock (the "Unconverted Preferred Stock"), the holder, solely at such holder's option, can elect to, at any time after receipt of notice from the Company that there is Unconverted Preferred Stock, to void the holder's Conversion Notice as to the number of shares of Common Stock the Company is unable to issue and retain or have returned, as the case may be, the certificates for the shares of the Unconverted Preferred Stock.

(b) **Mechanics of Fulfilling Holder's Election.** The Company shall immediately send via facsimile to a holder of Series B Preferred Stock, upon receipt of a facsimile copy of a Conversion Notice from such holder which cannot be fully satisfied as described in Section 8(a) above, a notice of the Company's inability to fully satisfy such holder's Conversion Notice (the "Inability to Fully Convert Notice"). Such Inability to Fully Convert Notice shall indicate (i) the reason why the Company is unable to fully satisfy such holder's Conversion Notice, and (ii) the number of shares of Series B Preferred Stock which cannot be converted.

9. Automatic Conversion.

(a) **Automatic Conversion Events.** All outstanding shares of Series B Preferred Stock shall be automatically converted into Common Stock at the Conversion Rate upon the earlier to occur of (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) December 31, 2012 (each, an "Automatic Conversion Event").

(b) **Mechanics of Automatic Conversion.** Upon the occurrence of an Automatic Conversion Event, the outstanding Series B Preferred Stock shall be converted into Common Stock automatically without any further action by the holders of such shares and whether or not the certificates representing such shares are surrendered to the Company or its transfer agent; provided, however, that the Company shall not be obligated to issue certificates evidencing the Common Stock issuable upon such conversion unless the certificates evidencing such Series B Preferred Stock are either delivered to the Company or its transfer agent as provided below, or the holder certifies to the Company or its transfer agent that such certificates have been lost, stolen or destroyed and executes an agreement satisfactory to the Company to indemnify the Company from any loss incurred by it in connection with such certificates. Upon surrender by any holder of the certificates formerly representing shares of Series B Preferred Stock to the Company or the transfer agent, there shall be issued and delivered to such holder promptly in its name as shown on such surrendered certificate or certificates, a certificate or certificates for the number of shares of Common Stock into which the shares of Series B Preferred Stock surrendered were converted on the date on which such automatic conversion occurred, and the Company shall promptly pay in cash (at the fair market value per share of Common Stock determined by the Board of Directors as of the date of conversion) the value of any fractional share of Common Stock otherwise issuable to any holder of

shares of Series B Preferred Stock being converted. Until surrendered as provided above, each certificate formerly representing Series B Preferred Stock shall be deemed for all corporate purposes to represent the number of shares of Common Stock resulting from such automatic conversion.

(c) Inability to Convert. Notwithstanding the provisions of Section 9(a) if, upon the occurrence of an Automatic Conversion Event, the Company cannot issue shares of Common Stock to fully effect the conversion for any reason, including, without limitation, because the Company (i) does not have a sufficient number of shares of Common Stock authorized and available, (ii) is otherwise prohibited by applicable law or by the rules or regulations of any stock exchange, interdealer quotation system or other self-regulatory organization with jurisdiction over the Company or its securities from issuing all of the Common Stock which is to be issued to a holder of Series B Preferred Stock, or (iii) the conversion would be prohibited by the provisions of Section 7 hereof and such prohibition has not been waived by the holder, then the Company shall issue as many shares of Common Stock as it is able to issue, and with respect to the unconverted Series B Preferred Stock (the “ Unconverted Preferred Stock ”), deliver to the holder a certificate for the shares of the Unconverted Preferred Stock. In the event that the Company is thereafter able to convert the Unconverted Preferred Stock, it shall so notify the holder in writing, and such notice shall be deemed to be an Automatic Conversion Event for purposes of this Section 9.

10. Vote to Change the Terms of Preferred Stock. The affirmative vote at a meeting duly called for such purpose, or the written consent without a meeting, of the holders of not less than a majority of the then outstanding shares of Series B Preferred Stock, shall be required for any change to this Certificate of Designation or the Company’s Certificate of Incorporation that would amend, alter, change or repeal any of the powers, designations, preferences and rights of the Series B Preferred Stock.

11. Lost or Stolen Certificates. Upon receipt by the Company of evidence satisfactory to the Company of the loss, theft, destruction or mutilation of any certificates representing the shares of Series B Preferred Stock, and, in the case of loss, theft or destruction, of any indemnification undertaking by the holder to the Company and, in the case of mutilation, upon surrender and cancellation of such certificate(s), the Company shall execute and deliver new preferred stock certificate(s) of like tenor and date.

12. Remedies, Characterizations, Other Obligations, Breaches and Injunctive Relief. The remedies provided in this Certificate of Designation shall be cumulative and in addition to all other remedies available under this Certificate of Designation, at law or in equity (including a decree of specific performance and/or other injunctive relief), no remedy contained herein shall be deemed a waiver of compliance with the provisions giving rise to such remedy and nothing herein shall limit a holder's right to pursue actual damages for any failure by the Company to comply with the terms of this Certificate of Designation. Amounts set forth or provided for herein with respect to payments, conversion and the like (and the computation thereof) shall be the amounts to be received by the holder thereof and shall not, except as expressly provided herein, be subject to any other obligation of the Company (or the performance thereof). The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the holders of the Series B Preferred Stock and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the holders of the Series B Preferred Stock shall be entitled, in addition to all other available remedies, to an injunction restraining any breach, without the necessity of showing economic loss and without any bond or other security being required.

13. Specific Shall Not Limit General; Construction. No specific provision contained in this Certificate of Designation shall limit or modify any more general provision contained herein.

14. Failure or Indulgence Not Waiver. No failure or delay on the part of a holder of Series B Preferred Stock in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other right, power or privilege.

Subsidiaries of Navidea Biopharmaceuticals, Inc.

Subsidiaries	Jurisdiction of Incorporation	Percentage Owned by Registrant
Cardiosonix Ltd.	Israel	100%
Navidea Biopharmaceuticals Limited	United Kingdom	100%
Macrophage Therapeutics, Inc.	Delaware, United States	99.9%

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Navidea Biopharmaceuticals, Inc. on Form S-3 (File Nos. 333-195806, 333-193330, 333-184173, 333-173752, 333-168485, 333-76151, and 333-15989) and Form S-8 (Nos. 33-81410, 333-119219, 333-130636, 333-130640, 333-153110, 333-158323, 333-183317, 333-05143, 333-21053, 333-05143, and 333-198716) of our report dated March 31, 2017, with respect to our audit of the consolidated financial statements of Navidea Biopharmaceuticals, Inc. as of December 31, 2016 and for the year then ended and our report dated March 31, 2017 with respect to our audit of the effectiveness of internal control over financial reporting of Navidea Biopharmaceuticals, Inc. as of December 31, 2016, which reports are included in this Annual Report on Form 10-K of Navidea Biopharmaceuticals, Inc. for the year ended December 31, 2016.

Our report on the effectiveness of internal control over financial reporting expressed an adverse opinion because of the existence of material weaknesses.

/s/ Marcum llp

New Haven, Connecticut
March 31, 2017

Consent of Independent Registered Public Accounting Firm

Navidea Biopharmaceuticals, Inc.
Dublin, Ohio

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-195806) and Form S-8 (No. 333-119219, 333-130636, 333-130640, 333-153110, 333-158323, 333-183317 and 333-198716) of Navidea Biopharmaceuticals, Inc. of our report dated March 23, 2016, relating to the consolidated financial statements of Navidea Biopharmaceuticals, Inc., which appear in this Form 10-K.

/s/ BDO USA, LLP

Chicago, Illinois
March 31, 2017

POWER OF ATTORNEY

Each of the undersigned officers and directors of Navidea Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby constitute and appoint Michael M. Goldberg, M.D. and Jed A. Latkin as his or her agents and lawful attorneys-in-fact, or either one of them individually with power to act without the other, as his or her agent and lawful attorney-in-fact, in his or her name and on his or her behalf, and in any and all capacities stated below:

- To sign and file with the United States Securities and Exchange Commission the Annual Report of the Company on Form 10-K (the "Annual Report") for the fiscal year ended December 31, 2016, and any amendments or supplements to such Annual Report; and
- To execute and deliver any instruments, certificates or other documents which they shall deem necessary or proper in connection with the filing of such Annual Report, and generally to act for and in the name of the undersigned with respect to such filing as fully as could the undersigned if then personally present and acting.

Each agent named above is hereby empowered to determine in his discretion the times when, the purposes for, and the names in which, any power conferred upon him herein shall be exercised and the terms and conditions of any instrument, certificate or document which may be executed by him pursuant to this instrument.

This Power of Attorney shall not be affected by the disability of any of the undersigned or the lapse of time.

The validity, terms and enforcement of this Power of Attorney shall be governed by those laws of the State of Ohio that apply to instruments negotiated, executed, delivered and performed solely within the State of Ohio.

This Power of Attorney may be executed in any number of counterparts, each of which shall have the same effect as if it were the original instrument and all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the undersigned have executed this Power of Attorney effective as of March 31, 2017.

<i>Signature</i>	<i>Title</i>
<u>/s/ Michael M. Goldberg</u> Michael M. Goldberg, M.D.	President, Chief Executive Officer and Director (principal executive officer)
<u>/s/ Jed A. Latkin</u> Jed A. Latkin	Interim Chief Operating Officer and Chief Financial Officer (principal financial officer and principal accounting officer)
<u>/s/ Eric K. Rowinsky</u> Eric K. Rowinsky, M.D.	Chairman of the Board of Directors
<u>/s/ Anthony S. Fiorino</u> Anthony S. Fiorino, M.D., Ph.D.	Director
<u>/s/ Mark I. Greene</u> Mark I. Greene, M.D., Ph.D., FRCP	Director
<u>/s/ Y. Michael Rice</u> Y. Michael Rice	Director

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael M. Goldberg, M.D. certify that:

1. I have reviewed this annual report on Form 10-K of Navidea Biopharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 31, 2017

/s/ Michael M. Goldberg

Michael M. Goldberg, M.D.
President and Chief Executive Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jed A. Latkin, certify that:

1. I have reviewed this annual report on Form 10-K of Navidea Biopharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 31, 2017

/s/ Jed A. Latkin

Jed A. Latkin
Interim Chief Operating Officer and Chief Financial Officer

**CERTIFICATION OF PERIODIC FINANCIAL REPORT PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002, 18 U.S.C. SECTION 1350**

The undersigned hereby certifies that he is the duly appointed and acting Chief Executive Officer of Navidea Biopharmaceuticals, Inc. (the "Company") and hereby further certifies as follows:

(1) The periodic report containing financial statements to which this certificate is an exhibit fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the periodic report to which this certificate is an exhibit fairly presents, in all material respects, the financial condition and results of operations of the Company.

In witness whereof, the undersigned has executed and delivered this certificate as of the date set forth opposite his signature below.

March 31, 2017

/s/ Michael M. Goldberg

Michael M. Goldberg, M.D.
President and Chief Executive Officer

**CERTIFICATION OF PERIODIC FINANCIAL REPORT PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002, 18 U.S.C. SECTION 1350**

The undersigned hereby certifies that he is the duly appointed and acting Chief Financial Officer of Navidea Biopharmaceuticals, Inc. (the “Company”) and hereby further certifies as follows:

(1) The periodic report containing financial statements to which this certificate is an exhibit fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the periodic report to which this certificate is an exhibit fairly presents, in all material respects, the financial condition and results of operations of the Company.

In witness whereof, the undersigned has executed and delivered this certificate as of the date set forth opposite his signature below.

March 31, 2017

/s/ Jed A. Latkin

Jed A. Latkin

Interim Chief Operating Officer and Chief Financial Officer
