NAVIDEA BIOPHARMACEUTICALS, INC.
Form 10-K
March 15, 2019

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, 2018

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	31-1080091

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4995 Bradenton Avenue, Suite 240, Dublin, Ohio	43017-3552
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

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 every Interactive Data File required to be submitted 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 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, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-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, 2018 was $35,842,392.

The number of shares of common stock outstanding on March 1, 2019 was 200,690,700.

DOCUMENTS INCORPORATED BY REFERENCE

None.

The Private Securities Litigation Reform Act of 1995 (the "PSLRA") 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 PSLRA. The words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," "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, our history of operating losses and uncertainty of future profitability, accumulated deficit, future capital needs, the outcome of any pending litigation, uncertainty of capital funding, dependence on royalties and grant revenue, limited product line and distribution channels, competition, risks of development of new products, our ability to maintain effective control over financial reporting, our ability to comply with NYSE American continued listing standards, 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 American: 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 Tc99m tilmanocept, 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 rights, 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.

Upon closing of the Asset Sale, the Supply and Distribution Agreement, dated November 15, 2007, as amended, 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).

Other than Tc99m 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.

Our business is focused on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform and NAV4694, and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by Macrophage Therapeutics, Inc. See Note 18 to the consolidated financial statements for more information about our business segments.

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 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. Following the sale of the GDS business and the subsequent strategic repositioning as a precision medicines company, the Company in-licensed 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 the Company would restructure its development efforts to focus on cost effective development of the Manocept platform and divest its neuro-tracer product candidates. In April 2015, the Company entered into an agreement with Alseres Pharmaceuticals, Inc. ("Alseres") to terminate the NAV5001 sub-license agreement. In April 2018, the Company executed an agreement to provide Meilleur Technologies, Inc. ("Meilleur") worldwide rights to conduct research using NAV4694, as well as an exclusive license for the development and commercialization of NAV4694 in Australia, Canada, China, and Singapore. Meilleur also has an option to commercialize worldwide.

In December 2014, we announced the formation of a new business unit to further explore therapeutic applications for the Manocept platform, which was incorporated as Macrophage Therapeutics, Inc. ("MT") in January 2015 as a majority-owned subsidiary of Navidea. Navidea also granted MT an exclusive sublicense for certain therapeutic applications of the Manocept technology. MT has developed processes for producing the first two therapeutic Manocept immuno-constructs, MT-1002, designed to specifically target and kill activated CD206+ macrophages by delivering doxorubicin, and MT-2002, designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent. MT has contracted with independent facilities to produce sufficient quantities of the MT-1002 and MT-2002 agents along with the concomitant analytical standards, to provide material for planned preclinical animal studies and future clinical trials.

In August 2018, the Company entered into an agreement (the "Agreement") with Dr. Michael Goldberg related to his resignation from his positions as an executive officer and a director of Navidea. Among other things, the Agreement provided that Dr. Goldberg would become Chief Executive Officer of MT, and that MT would redeem all of Dr. Goldberg's MT preferred stock and issue to Dr. Goldberg MT super voting common stock equal to 5% of the outstanding shares of MT, subject to execution of Definitive Agreements. As of the date of filing of this Annual Report on Form 10-K, the Definitive Agreements have not yet been signed.

On February 11, 2019, Dr. Goldberg represented to the MT Board that he had, without MT Board or shareholder approval, created a subsidiary of MT, transferred all of the assets of MT into the subsidiary, and then issued himself stock in the subsidiary. On February 19, 2019, Navidea notified MT that it was terminating the sublicense effective March 1, 2019 because MT became insolvent in violation of the sublicense agreement. On February 20, 2019, the Board of Directors of MT removed Dr. Goldberg as President and Chief Executive Officer of MT and from any other office of MT to which he may have been appointed or in which he was serving. Dr. Goldberg remains a member of the MT Board, together with Michael Rice and Dr. Claudine Bruck. Mr. Rice and Dr. Bruck remain members of the board of directors of Navidea. The MT Board then appointed Mr. Latkin to serve as President and Chief Executive Officer of MT.

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the United States District Court for the Southern District of New York, alleging breach of the Agreement, as well as a breach of the covenant of good faith and fair dealing and to obtain a declaratory judgment that Navidea's performance under the Agreement is excused and that Navidea is entitled to terminate the Agreement as a result of Dr. Goldberg's actions. Also on February 20, 2019, MT initiated a suit against Dr. Goldberg in the Court of Chancery of the State of Delaware, alleging, among other things, breach of fiduciary duty as a director and officer of MT and conversion, and to obtain a declaratory judgment that the transactions Dr. Goldberg caused MT to enter into are void. On March 13, 2019, the Court of Chancery entered an order maintaining status quo, which provided, among other things, that MT's board of directors may authorize any act or transaction on behalf of the Company, and that without prior written authorization of the MT board, Dr. Goldberg shall not hold himself out as CEO of MT or purport to act or authorize any action on behalf of MT except as authorized by the MT board.

On March 7, 2019, Dr. Goldberg filed a complaint against Navidea and MT in the United States District Court for the Southern District of New York. The Complaint alleges a breach of contract claim against both Navidea and MT for failure to pay to Dr. Goldberg funds allegedly due to him under the Promissory Note, dated July 25, 2012, made by the Company in favor of Platinum-Montaur Life Sciences LLC (the "Platinum Note"). The Complaint further alleges a breach of contract claim against Navidea due to Navidea's failure to issue 23.5 million shares to Dr. Goldberg, to issue MT Super Voting Common Stock, by removing Dr. Greene from the MT Board of Directors, by appointing Mr. Rice and Dr. Bruck to the MT Board of Directors, and by terminating Dr. Goldberg as CEO of MT.

Our Technology and Product Candidates

Our primary development efforts over the last several years were focused on diagnostic products, including Lymphoseek which was sold to Cardinal Health 414 in March 2017. Our more recent initiatives have been focused exclusively on diagnostic and therapeutic line extensions based on our Manocept platform.

Manocept Platform - Diagnostics and Therapeutics Background

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed primarily on activated macrophages. This flexible and versatile platform serves as a molecular engine for purpose-built targeted imaging molecules that may significantly impact patient care by providing enhanced diagnostic accuracy, clinical decision-making, and target-specific treatment. This CD206-targeted drug platform is applicable to a range of diagnostic modalities, including single photon emission computed tomography ("SPECT"), positron emission tomography ("PET"), gamma-scanning (both imaging and topical) and 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-involved diseases. The FDA-approved sentinel node/lymphatic mapping agent, Tc99m tilmanocept, is representative of the ability to successfully exploit this mechanism to develop powerful new products and to expand this technology into additional diagnostic and therapeutic applications.

Activated macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. Impairment of the macrophage-driven disease mechanisms is an area of increasing and proven 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 up to 700 million worldwide, making macrophage-mediated diseases an area of remarkable clinical importance. There are many recognized disorders having macrophage involvement, including rheumatoid arthritis ("RA"), atherosclerosis/vulnerable plaque, nonalcoholic steatohepatitis ("NASH"), inflammatory bowel disease, systemic lupus erythematosus, Kaposi's sarcoma ("KS"), leishmaniosis, and others that span general clinical areas in oncology, autoimmunity, infectious diseases, cardiology, CNS diseases, and inflammation. For the near term, we have selected target diseases that may, if successfully developed, benefit from this technology.

Manocept Platform – Immuno-Diagnostics Clinical Data

Rheumatoid Arthritis

Two Tc99m tilmanocept dose escalation studies in RA have been completed. The first study was completed and included 18 subjects (nine with active disease and nine healthy subjects) dosed subcutaneously with 50 and 200 µg/2mCi Tc99m tilmanocept (ClinicalTrials.gov NCT02683421). The results of this study were presented at five international meetings, including Biotechnology Innovation Organization ("BIO"), Society of Nuclear Medicine and Molecular Imaging ("SNMMI"), and The American College of Rheumatology ("ACR"). In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have completed a Phase 1/2 study involving intravenous ("IV") dosing of 39 subjects with IV-administered Tc99m tilmanocept (ClinicalTrials.gov NCT02865434). In conjunction with this study, we have completed pharmacokinetic, pharmacodynamics and radiation dosimetry phases in human subjects as well. The majority of the costs of these studies have been supported through a Small Business Innovation Research ("SBIR") grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1). Results were presented at the June 2018 SNMMI meeting. These studies have been combined and submitted for peer review publication and full published results will follow.

Cardiovascular Disease ("CV")

In collaboration with researchers at Massachusetts General Hospital, Navidea has completed one and initiated a second clinical study evaluating Tc99m tilmanocept's ability to enable imaging of atherosclerotic plaques. Results of these studies provide strong preliminary evidence of the potential of Tc99m tilmanocept to accumulate specifically in and enable imaging of non-calcified atherosclerotic plaques. Non-calcified atherosclerotic plaques include plaques with morphologies indicating a high risk of rupture. Rupture of such plaques causes myocardial infarctions (heart attacks) and a significant portion of ischemic strokes. The studies compared aortic Tc99m tilmanocept uptake imaged by SPECT/CT in clinically asymptomatic subjects with intermediate Framingham Risk Scores ("FRS") who were infected with Human Immunodeficiency Virus ("HIV") as compared to healthy, uninfected, FRS and age-matched subjects. Tc99m tilmanocept SPECT/CT images were compared to aortic images of the same subjects obtained by

contrast enhanced coronary computed tomography angiography and/or [18F]NaF PET/CT.

A nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc99m tilmanocept product dosed subcutaneously is complete (ClinicalTrials.gov NCT02542371). The results of this study were presented at two major international meetings (Conference on Retroviruses and Opportunistic Infections ("CROI") and SNMMI, 2017) and published in early release in the *Journal of Infectious Diseases* in January 2017 (published in the circulated version, *Journal of Infectious Diseases* (2017) **215** (8): 1264-1269), confirming that the Tc99m tilmanocept product can both quantitatively and qualitatively target non-calcified plaque in the aortic arch of Acquired Immunodeficiency Syndrome ("AIDS") patients (supported by NIH/NHLBI Grant 1 R43 HL127846-01).

We have also commenced a second Phase1/2 study in cooperation with Massachusetts General Hospital in subjects with HIV that expands the original study in both the scope of the drug administration as well as the diagnostic assessment of the subjects. This study will enroll up to 24 AIDS subjects and healthy controls in imaging non-calcified plaque using IV-administered Tc99m tilmanocept and will expand the initial investigation to the assessment of aortic plaque as well as carotid and coronary arteries. Initial images from this study are currently being evaluated.

Kaposi's Sarcoma

KS is a serious and potentially life-threatening illness, which in the United States occurs disproportionately in persons infected with HIV and in organ transplant patients. The prognosis for patients with treatment-resistant KS is poor with high probabilities for mortality and greatly diminished quality of life. We initiated and completed a study of KS in 2015 (ClinicalTrials.gov NCT022201420), and received additional funding from the National Institutes of Health ("NIH") in 2016 to continue diagnostic studies in this disease. The new support not only continues the imaging of the cutaneous form of this disease but expands this to imaging of visceral disease via IV administration of Tc99m tilmanocept (NIH/NCI 1 R44 CA192859-01A1; ClinicalTrials.gov NCT03157167). This now-escalated study includes a pathology/biopsy component as well as an imaging component to determine pathology concordance with image assessment. We received Institutional Review Board approval of the clinical protocol, we initiated a Phase 1/2 clinical study in KS in 2017, and the trial is currently ongoing.

Colorectal Cancer ("CRC") and Synchronous Liver Metastases

During the first quarter of 2017, we initiated an imaging study in subjects with CRC and liver metastases via IV administration of Tc99m tilmanocept. This study was supported through a SBIR grant (NIH/NCI 1 R44 CA1962783-01A1; ClinicalTrials.gov NCT03029988). The trial intended to enroll up to 12 subjects with dose modification. After an interim analysis of the first three completed subjects, a decision was made to not continue with the trial and the study is now closed. An initial presentation took place at SNMMI in June of 2018. An additional report has been submitted to the National Cancer Institute ("NCI") on the early results of this study.

Nonalcoholic Steatohepatitis

We have concluded a clinical study (ClinicalTrials.gov NCT03332940) that was originally designed to enroll 12 subjects with IV administration of Tc99m tilmanocept and an imaging comparator to identify and quantify the extent of NASH lesions in human patients. A semiquantitative evaluation of the images from the first six subjects indicated that imaging the remaining six subjects planned in the study may not sufficiently further our knowledge of Tc99m tilmanocept imaging in individuals with NASH to justify continuing the study using the current protocol. The study is now complete. Ongoing quantitative analyses of the images from the first six subjects will determine if future studies in subjects with NASH are likely to be productive. Initial results were presented at the NASH Summit in Boston in April 2018, and the results are available on Navidea's website.

Biomarker Application and Qualification

In November 2017, the Company commenced the qualification of the biomarker CD206 with the FDA Biomarker Section of The Center for Drug Evaluation and Research ("CDER"). As per FDA protocol, Navidea submitted a draft letter of intent ("LOI") to CDER prior to the November 2017 meeting. According to the CDER directive, "the Biomarker Qualification Program was established to support the CDER's work with external stakeholders to develop biomarkers that aid in the drug development process. Through the FDA's Biomarker Qualification Program, an entity may request regulatory qualification of a biomarker for a particular context of use ("COU") in drug development." Following the meeting with the FDA, and because of Navidea's data sets and the general external publication database, Navidea, in conjunction with FDA, is now reviewing the LOI with the FDA's recommended consultants. Navidea has revised the LOI draft strategy in order to expedite the application process. In March 2018, Navidea had a follow-up meeting with the FDA's assigned strategist, during which the potential to further narrow the LOI elements was reviewed. Navidea is continuing the process of finalizing the COU LOI and providing the background data sets for qualification review with the FDA/CDER. Additional meetings have taken place and the pursuit of this qualification is progressing well.

Macrophage Therapeutics Background

In December 2014, the Company formed a new business unit to further explore therapeutic applications for the Manocept platform. In January 2015, Navidea incorporated the business unit as MT, a majority-owned subsidiary of Navidea. MT has developed processes for producing the first two therapeutic Manocept immuno-constructs, MT-1002, designed to specifically target and kill activated CD206+ macrophages by delivering doxorubicin, and MT-2002, designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent. MT has contracted with independent facilities to produce sufficient quantities of the MT-1002 and MT-2002 agents along with the concomitant analytical standards, to provide material for planned preclinical animal studies and future clinical trials.

See Notes 10 and 15 to the accompanying consolidated financial statements.

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

MT has been set up to pursue the therapeutic drug delivery model. This model enables the Company to leverage its technology over many potential disease applications and with multiple partners simultaneously without significant capital outlays. To date, the Company has developed two lead families of therapeutic products. The MT-1000 class is designed to deplete activated macrophages via apoptosis. The MT-2000 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 have already reported on the peripheral infectious disease aspects of KS, including HIV and HHV8 (CROI, Boston 2016, and KS HHV8 Summit Miami 2015). As noted, we continue this work funded by the NIH/NIAID and NCI. The Company has completed preclinical studies employing both MT 1000-class and 2000-class therapeutic conjugates of Manocept. The positive results from these studies are indicative of Manocept's specific targeting supported by its strong binding affinity to CD206 receptors. This high degree of specificity is a foundation of 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.

Kaposi's Sarcoma

The novel MT-1000 class constructs are designed to specifically deliver doxorubicin, a chemotoxin, which can kill KS tumor cells and their tumor-associated macrophages, potentially altering the course of cancer. We have received

additional funding to continue therapeutic studies in this disease with the goal of completing an investigational new drug ("IND") submission for a Manocept construct (MT-1000 class of compounds) consisting of tilmanocept linked to doxorubicin for the treatment of KS. The first part of the grant, now complete, supported analyses including *in vitro* and cell culture studies, to be followed by Parts 2 and 3 FDA-required preclinical animal testing studies. 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 in selected KS subjects (supported by NIH/NCI 1 R44 CA206788-01).

Nonalcoholic Fatty Liver Disease ("NAFLD")

NAFLD is a spectrum of liver disorders and is defined by the presence of steatosis in more than 5% of hepatocytes with little or no alcohol consumption. NASH is the most extreme form of NAFLD. A major characteristic of NASH involves cells undergoing lipotoxicity, releasing endogenous signals prompting the accumulation of various macrophages to assess the damage. Studies have shown that levels of endogenous molecular inflammatory signals positively correlate with inflammation, hepatocyte ballooning, and other NAFLD symptoms. We have developed a molecular delivery technology capable of targeting disease-causing macrophages by selectively binding to the CD206 receptor. Selective binding and efficient delivery of this agent diminishes the potential of interfering more broadly with the normal function of the immune system.

We have completed five *in vivo* studies employing our MT-1002 and MT-2002 Manocept conjugates in a mouse model of NAFLD/NASH and liver fibrosis. The NALFD scores, which correlate to the agents' effectiveness, were significantly reduced, with all the activity related to inflammation and "ballooning" scores. Fibrosis decreased significantly when compared to the control in the later dosing arm of the study. Liver weights did not differ during any phase of the study between control and agent-treated groups, nor was there any evidence of damage to the roughly 30% of the liver made up of un-activated macrophages called Kupffer cells. MT-1002 and MT-2002 both significantly reduced key disease assessment parameters in the *in vivo* STAM™ NASH model. We believe these agents present themselves as potential clinically effective candidates for further evaluation. We continue to use this model to further assess the activity of our agents.

Other Immunotherapeutic Applications

We have completed an expanded series of predictive *in vitro* screening tests of the MT-1002 and MT-2002 therapeutic conjugates against the Zika and Dengue viruses, which included infectivity and viral replication inhibition effectiveness as well as dose finding studies and mechanisms of action, the latter based on conjugate structures. We have also completed a series of predictive *in vivo* screening tests of the MT-1002 and MT-2002 therapeutic conjugates against Leishmaniosis, which included host cell targeting and killing effectiveness as well as dose finding studies and mechanisms of action. A portion of the results from the *in vivo* Leishmaniosis study, completed in conjunction with the National Institute of Allergy and Infectious Diseases/NIH, was recently published in the *Journal of Experimental Medicine (*published in the circulated version *Journal of Experimental Medicine* 2018 Jan 2;215(1):357-375). The results from all evaluations were positive and have provided a basis for moving forward with additional *in vivo* testing of the selected conjugates. We have selected collaborators for these *in vivo* studies, which we expect will take place over the next four to six months. We will provide updates as information becomes available on future testing.

The Company continues to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform, including ongoing studies in KS, RA and infectious diseases. 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.

NAV4694 (Sublicensed)

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 Tc99m 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. In April 2018, the Company executed an agreement to provide Meilleur, a wholly-owned subsidiary of Cerveau Technologies, Inc. ("Cerveau"), worldwide rights to conduct research using NAV4694, as well as an exclusive license for the development and commercialization of NAV4694 in Australia, Canada, China, and Singapore. Meilleur also has an option to commercialize worldwide.

Market Overview

Tc99m Tilmanocept – Cancer Market Overview

Cancer is the second leading cause of death in the United States. The American Cancer Society ("ACS") estimates that cancer will cause over 600,000 deaths in 2019 in the United States alone. Additionally, the ACS estimates that approximately 1.7 million new cancer cases will be diagnosed in the United States during 2019. The Agency for Healthcare Research and Quality has estimated that the direct medical costs for cancer in the United States for 2015 were $80.2 billion. Cancer is also the second leading cause of death in Europe. The World Health Organization reports more than 3.7 million new cases and 1.9 million deaths in Europe each year.

Tc99m tilmanocept is approved by the 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, head and neck cancer, melanoma or squamous cell carcinoma of the oral cavity. Tc99m 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. If the potential of Tc99m 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, gynecologic, and non-small cell lung.

Manocept Diagnostics and Macrophage Therapeutics Market Overview

Impairment of the macrophage-driven disease mechanism is an area of increasing focus in medicine. 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. The number of people affected by all the inflammatory diseases combined is estimated at more than 40 million in the United States, making these macrophage-mediated diseases an area of significant clinical importance. The Arthritis Foundation estimates that RA alone affects over 1.5 million people in the United States and as much as 1% of the worldwide population. Based on 2005 U.S. Medicare/Medicaid data, total annual societal costs of RA are estimated to be $39.2 billion. 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 5.7 million Americans had AD in 2018. On a global basis, Alzheimer's Disease International estimated in 2015 that there were 46.8 million people living with dementia, and this number is believed to be close to 50 million people in 2017. This number is expected to almost double every 20 years, reaching 75 million in 2030 and over 130 million in 2050. AD is the sixth-leading cause of death in the U.S. 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 to 2015, deaths from AD have risen 123 percent while deaths attributed to the number one cause of death, heart disease, decreased 11 percent during the same period. AA estimates that total costs for AD care was approximately $259.0 billion in 2017. AA also estimates that there are over 16 million AD and dementia caregivers providing 18.4 billion hours of unpaid care valued at over $232.0 billion.

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 United States, where institutions typically rely on radiopharmaceutical products that 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 Tc99m tilmanocept commercialization in Europe, we have chosen a specialty pharmaceutical strategy that should be supportive of premium product positioning and reinforce Tc99m 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 ("EU") 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 Tc99m tilmanocept Marketing Authorization to SpePharm in January 2017. SpePharm is also 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 $2.0 million, and is entitled to milestones totaling up to an additional $5.0 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. During the second quarter of 2017, SpePharm launched Tc99m tilmanocept in select EU markets, providing a number of early adopters with sample doses to provide exposure to the product. EU sales commenced during the third quarter 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 Tc99m tilmanocept in China. In exchange, Navidea will earn revenue based on unit sales to Sinotau, royalties based on Sinotau's sales of Tc99m tilmanocept and 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 Tc99m tilmanocept approval by the China Food and Drug Administration ("CFDA"). Upon approval, Sinotau will be responsible for all Tc99m 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 June 2017, Navidea entered into an exclusive license and distribution agreement with Sayre Therapeutics ("Sayre") for the development and commercialization of Tc99m tilmanocept in India. Sayre specializes in innovative treatments and medical devices commercialization in South Asia. Under the terms of the agreement, Navidea received a $100,000 upfront payment and is eligible to receive milestone payments and double-digit royalties associated with the sale of Tc99m tilmanocept in India. Tc99m tilmanocept has not yet received marketing approval in India.

Tc99m tilmanocept is in various stages of approval in other global markets and sales to this point in these markets, to the extent there were any, have not been material. However, we believe that with international partnerships to complement our positions in the EU, China and India, we will help establish Tc99m tilmanocept as a global leader in lymphatic mapping, as we are not aware of any other company that has a global geographic range. However, it is possible that Tc99m tilmanocept will never achieve regulatory approval in any market outside the United States or EU, or if approved, that it may not achieve market acceptance in any market. We may also experience difficulty in securing collaborative partners for other global markets or radiopharmaceutical products, or successfully negotiating acceptable terms for such arrangements. See Item 1A - “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.

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 Tc99m 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 50-microgram 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 Tc99m tilmanocept Marketing Authorization to SpePharm, our contract with Gipharma was transferred to SpePharm. We may not be successful in completing future agreements for the supply of Tc99m tilmanocept on terms acceptable to the Company, or at all. See Item 1A - “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 Item 1A - “Risk Factors.”

Tc99m Tilmanocept Competition – Currently Approved Indications

Surgeons who practice the lymphatic mapping procedure for which Tc99m 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.”

Rheumatoid Arthritis Competition

Currently, no single test is available to diagnose and monitor RA. Rather, a rheumatologist will make a diagnosis based on several procedures that may include a physical exam, blood tests, and/or imaging tests, among others. The Arthritis Foundation states that the goals of RA treatment are to relieve symptoms, stop inflammation, prevent joint and organ damage, improve physical function and well-being, and reduce long-term complications. Medications for the treatment of RA currently fall into two categories: drugs that ease symptoms, such as nonsteroidal anti-inflammatory drugs, and drugs that slow disease activity. Drugs that slow disease activity include corticosteroids, disease-modifying antirheumatic drugs, biologics, and Janus kinase inhibitors. Many of these drugs are produced and sold by large pharmaceutical companies, including AbbVie, Amgen, Bristol Meyers Squibb, Johnson & Johnson, Merck, Pfizer, and Roche, among others.

Patents and Proprietary Rights

The patent position of biotechnology companies, including Navidea, 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. Our patent applications or those licensed to us may not result in additional patents being issued, and our patents or those licensed to us may not afford protection against competitors with similar technology; these patents may be designed around by others or others may obtain patents that we would need to license or design around.

We also rely upon unpatented trade secrets. Others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets, or disclose such technology, or we may not be able to 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. However, these agreements may not 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. However, these measures may not be adequate to protect our trade secrets from unauthorized access or disclosure. See Item 1A - “Risk Factors.”

Tilmanocept Intellectual Property

Tilmanocept is under license from UCSD to Navidea for the exclusive world-wide rights in all diagnostic and therapeutic uses of tilmanocept, except for the diagnostic use of Tc99m 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 Tc99m tilmanocept in the rest of the world, as well as a license to the intellectual property underlying the Manocept platform.

Tc99m tilmanocept and related compositions, including the Manocept backbone composition and methods of use, are the subject of multiple patent families totaling 44 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, and will expire in May 2020, however Navidea has applied for a patent term extension under the Hatch Waxman Act that would extend the term by five years due to time lost in regulatory review. 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, and some have been granted, extending the patent term to 2025. The composition of matter patent has also been issued in Japan, which will expire in 2020.

Patent applications have been filed 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 2034. Further patent applications have been filed by Navidea alone or with The Ohio State Innovation Foundation related to CD206 expressing cell-related disorders and diseases. These patents and/or applications would be expected to 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 2038.

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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. Such changes may 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, a warning letter, recall or safety alert, if it occurred, could have a material adverse effect on our company. See Item 1A - “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, the FDA review processes could delay our Company's introduction of new products in the United States 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 Item 1A - “Risk Factors.”

The U.S. Drug Approval Process

None of our drugs may be marketed in the United States until such drug has received FDA approval. The steps required before a drug may be marketed in the United States 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 New Drug Application (“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. Our drug candidates may not qualify for any of these programs, or, if a drug candidate does qualify, the review time may not be reduced or the product may not 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 United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all EU 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 European Commission granted marketing authorization for Tc99m 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 any approval may not 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. Our potential drug or biologic products may not be approved by the regulatory bodies or may not be approved on a timely or accelerated basis, or any approvals received may 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 may not be able to obtain all necessary licenses and permits and we may not 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 4995 Bradenton Avenue, Suite 240, 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 United States and/or other countries. Other trademarks or service marks appearing in this report may be trademarks or service marks of other owners.

Available Information

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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), and amendments to such filings, as soon as reasonably practicable after each is electronically filed with, or furnished to, the Securities Exchange Commission ("SEC"). We do not charge for access to and viewing of these reports. Information in the investor section and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference.

In addition, the public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, our filings with the SEC may be accessed through the SEC's website at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

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-36 of this Form 10-K.

Employees

As of March 1, 2019, we had 14 full-time and 5 part-time employees. None of our employees are represented by a collective bargaining agreement, we have not experienced any work stoppages, and we believe that our relationship with our employees is good.

Item 1A. Risk Factors

An investment in our common stock is highly speculative, involves a high degree of risk, and should be made only by investors who can afford a complete loss. You should carefully consider the following risk factors, together with the other information in this Form 10-K, including our financial statements and the related notes, before you decide to buy our common stock. 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, SpePharm AG, Sayre Therapeutics or Sinotau do not achieve commercial success with Tc99m 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 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.

Under the terms of our August 2014 agreement with Sinotau, as amended, Navidea is entitled to receive royalties and milestone payments based on Sinotau's sales of Tc99m tilmanocept. Upon approval by the CFDA, Sinotau will be responsible for all Tc99m tilmanocept sales, marketing, market access and medical affairs activities in China, excluding Hong Kong, Macau and Taiwan. Tc99m tilmanocept has not yet received marketing approval in China.

Under the terms of our March 2015 exclusive sublicense agreement with SpePharm, Navidea is entitled to receive royalty and milestone payments from SpePharm based on net sales derived from Tc99m tilmanocept. SpePharm commenced marketing of Tc99m tilmanocept in the EU during the third quarter of 2017.

Under the terms of our June 2017 agreement with Sayre, Navidea is eligible to receive milestone payments and royalties associated with the sale of Tc99m tilmanocept in India. Tc99m tilmanocept has not yet received marketing approval in India.

Cardinal Health 414, SpePharm, Sayre or Sinotau may never achieve commercial success in North America, the EU, India, China, or any other global market, they may never realize sales at levels necessary for us to achieve sales-based earnout, royalty or milestone payments, and such payments may never 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, among others, 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.

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 revenues from our Manocept-based product candidates may preclude us from continuing our research and development of these and other product candidates.

We may never 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 chemistry, manufacturing and control ("CMC") processes of drug production, can be interpreted in different ways that 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.

We may not be successful in securing and/or maintaining the necessary manufacturing, supply and/or radiolabeling capabilities for our product candidates in clinical development.

We may not be able to secure and/or 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 may not be able to establish an alternate source of supply 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.

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 European Medicines Agency (“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 Tc99m 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 United States 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 United States, 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. Tc99m tilmanocept is expected to continue to compete against sulfur colloid in the United States 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.

We may be exposed to business risk, including product liability claims for any 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 we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, whether arising out of product liability matters, cybersecurity matters, or from some other matter, that claim could have a material adverse effect on our results of operations.

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

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

Our currently held and licensed patents expire over the next one to eleven 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.

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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.

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.

A security breach or privacy violation that leads to disclosure of consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state and foreign breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue.

Despite our efforts to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend substantial additional resources to continue to protect against potential security breaches or to address problems caused by such attacks or any breach of our safeguards. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties.

The interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. Among other things, foreign privacy laws impose significant obligations on U.S. companies to protect the personal information of foreign citizens. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices, which could have a material adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

We do not currently carry cyber risk insurance. If we are subject to liability resulting from a security breach or other disruption in our information systems, we could be exposed to significant liability that could have a material adverse effect on our results of operations.

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. If our employees or other agents engage in such conduct, we might be held responsible and 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: (i) failure to comply with a variety of national and local laws of countries in which we do business, including restrictions on the import and export of certain intermediates, drugs, and technologies, (ii) failure to comply with a variety of U.S. laws including 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 final outcome of the Capital Royalty Partners II L.P. ("CRG") litigation and other litigation, including the outcome of any litigation involving Dr. Michael Goldberg;
- 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.

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. Research funding for life science research has increased more slowly during the past several years compared to previous years and has declined in some countries, and some grants have been frozen for extended periods of time or otherwise become unavailable to various institutions, sometimes without advance notice. Government funding of research and development is subject to the political process, which is inherently fluid and unpredictable. Other programs, such as homeland security or defense, or general efforts to reduce the federal budget deficit could be viewed by the U.S. government as a higher priority. These budgetary pressures may result in reduced allocations to government agencies that fund research and development activities. National Institute of Health and other research and development allocations have been

diminished in recent years by federal budget control efforts. The prolonged or increased shift away from the funding of life sciences research and development or delays surrounding the approval of government budget proposals may result in reduced research grant funding, which could delay development of our product candidates.

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

Our common stock has been listed on the NYSE American exchange since February 2011. The rules of NYSE American 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 American 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 American may consider suspending trading in, or removing the listing of, securities of an issuer that has stockholders' equity of less than (i) $6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years, (ii) $4.0 million if such issuer has sustained losses from continuing operations and/or net losses in three of its four most recent fiscal years, and (iii) $2.0 million if such issuer has sustained losses from continuing operations and/or net losses in two of its three most recent fiscal years. As of December 31, 2018 and 2017, Navidea had stockholders' equity of approximately $1.7 million and $11.4 million, respectively. In addition, the Company had stockholders' deficits for several years prior to December 31, 2017, and we may not be able to maintain stockholders' equity in the future. Even if an issuer has a stockholders' deficit, the NYSE American will not normally consider delisting securities of an issuer that fails to meet these requirements if the issuer has (1) average global market capitalization of at least $50,000,000; or total assets and revenue of $50,000,000 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. As of December 31, 2018, the Company's total value of market capitalization was approximately $19.4 million. Therefore, we do not currently meet these exceptions and there is a risk that our common stock may be delisted as a result of our failure to meet the minimum stockholders' equity requirement for continued listing. The NYSE American provides for an 18-month "cure period" for the Company to regain the minimum stockholders' equity requirement, however if the Company is unable to do so, the NYSE American may delist the Company's common stock.

The NYSE American 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 $0.10 per share.

On August 14, 2018, the Company received a Deficiency Letter from the NYSE American stating that Navidea was not in compliance with certain NYSE American continued listing standards relating to stockholders' equity. Specifically, the Deficiency Letter stated that Navidea is not in compliance with Section 1003(a)(ii) of the NYSE American Company Guide, which requires an issuer to have stockholders' equity of $4.0 million or more if it has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years. The Deficiency Letter noted that Navidea had stockholders' equity of $2.1 million as of June 30, 2018, and has reported net losses in four of its five most recent fiscal years ended December 31, 2017.

Navidea was required to submit a plan to the NYSE American by September 14, 2018 advising of actions it has taken or will take to regain compliance with the continued listing standards by February 14, 2020. Navidea submitted a plan by the deadline.

On October 25, 2018, the Company received an Acceptance Letter from the NYSE American that the Company's plan to regain compliance was accepted. The Acceptance Letter also stated that the NYSE American had inadvertently omitted an additional deficiency from the Deficiency Letter. Specifically, the Deficiency Letter should have stated that Navidea is not in compliance with Section 1003(a)(iii) of the NYSE American Company Guide, which requires an issuer to have stockholders' equity of $6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years. The Acceptance Letter noted that Navidea had stockholders' equity of $2.1 million as of June 30, 2018, and has reported losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2017.

The Company must provide quarterly updates to the NYSE American Staff concurrent with its interim/annual SEC filings. If Navidea fails to regain compliance with the stockholders' equity standards by February 14, 2020, the NYSE American may commence delisting procedures.

In addition, the Deficiency Letter stated that the Staff determined that the Company's securities have been selling for a low price per share for a substantial period of time and, pursuant to Section 1003(f)(v) of the NYSE American Company Guide, Navidea's continued listing is predicated on it effecting a reverse stock split of its Common Stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the Staff had determined to be no later than February 14, 2019. However, on January 28, 2019, the Company received a notice from the NYSE American that it has granted the Company an extension until March 31, 2019 to regain compliance with Section 1003(f)(v) of the NYSE American's continued listing standards. Navidea must regain compliance with the price standard by that date in order to be considered for continued trading through the end of February 14, 2020.

At the Company's 2018 Annual Meeting of Stockholders (the "Annual Meeting"), held on August 16, 2018, stockholders approved a reverse stock split of the Company's common stock, as determined by the Board of Directors at its discretion, of a ratio of not less than one-for-five and not more than one-for-twenty. The Board of Directors has not taken action to effect a reverse stock split as of the date of filing this Annual Report on Form 10-K. There can be no assurance that the Board of Directors will take steps to implement the reverse stock split, and if they do, such a reverse stock split may not be sufficient to enable the Company to maintain its listing on the NYSE American. Therefore, there is a continued risk that the shares will be delisted if action is not taken to the satisfaction of the NYSE American.

Navidea's Common Stock will continue to be listed on the NYSE American while it attempts to regain compliance with the listing standards noted above, subject to Navidea's compliance with other continued listing requirements. The Common Stock will continue to trade under the symbol "NAVB," but will have an added designation of ".BC" to indicate that Navidea is not in compliance with the NYSE American's listing standards. The NYSE American notification does not affect Navidea's business operations or its SEC reporting requirements and does not conflict with or cause an event of default under any of Navidea's material agreements.

The delisting of our common stock from the NYSE American 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.

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 $0.10 per share and as high as $0.42 per share during the 12-month period ended February 28, 2019. 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 United States 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, 2018 and ending on February 28, 2019, the average daily trading volume for our common stock on the NYSE American was approximately 450,000 shares. However, this trading volume may not be consistently maintained in the future. If the trading volume for our common stock decreases, there could be a relatively limited market for our common stock and the share price of our common stock would be more likely to be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market's perception of our business and announcements made by us, our competitors or parties with whom we have business relationships. There may also be fewer institutional investors willing to hold or acquire our common stock. Such a lack of liquidity in our common stock may make it difficult for us to issue additional securities for financing or other purposes or to otherwise arrange for any financing that we may need 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 American 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 American. 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 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.

Healthcare reform measures could hinder or prevent the commercial success of our products.

In March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, the Patient Protection and Affordable Care Act (the “PPACA”), which had far-reaching consequences for many healthcare companies, including diagnostic companies like ours. For example, if reimbursement for our products is substantially less than we or our customers expect, our business could be materially and adversely impacted. However, the future of the PPACA is uncertain and at this juncture there will be a period of uncertainty regarding the PPACA’s repeal, modification or replacement or the effect of the changes made to the PPACA under the Tax Cuts and Jobs Act of 2017, any of which could have long term financial impact on the delivery of and payment for healthcare in the United States.

Regardless of the impact of the PPACA on us, the U.S. government and other governments have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services in the United States and internationally, as well as the amount of reimbursement available from governmental agencies and other third-party payors.

Actual and anticipated changes to the regulations of the healthcare system and U.S. tax laws may have a negative impact on the cost of healthcare coverage and reimbursement of healthcare services and products.

The FDA and comparable agencies in other jurisdictions directly regulate many critical activities of life science, technology, and healthcare industries, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting, and product risk management. In both domestic and foreign markets, sales of products depend in part on the availability and amount of reimbursement by third-party payors, including governments and private health plans. Governments may regulate coverage, reimbursement, and pricing of products to control cost or affect utilization of products. Private health plans may also seek to manage cost and utilization by implementing coverage and reimbursement limitations. Substantial uncertainty exists regarding the reimbursement by third-party payors of newly approved healthcare products. The U.S. and foreign governments regularly consider reform measures that affect healthcare coverage and costs. Such reforms may include changes to the coverage and reimbursement of healthcare services and products. In particular, there have been recent judicial and Congressional challenges to the PPACA, which could have an impact on coverage and reimbursement for healthcare services covered by plans authorized by the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future.

In addition, various other healthcare reform proposals have emerged at the federal and state level. The recent changes to U.S. tax laws could also negatively impact the PPACA. We cannot predict what healthcare initiatives or tax law changes, if any, will be implemented at the federal or state level, however, government and other regulatory oversight and future regulatory and government interference with the healthcare systems could adversely impact our business.

We may not be able to maintain compliance with our internal controls and procedures.

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. 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.

The Company has experienced recurring net losses and has used significant cash to fund its operations, and we expect to continue to incur substantial operating losses and may be unable to obtain additional financing, causing

substantial doubt about our ability to continue as a going concern over the next twelve months from the filing of this Annual Report. The report of our independent registered public accounting firm includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm's report issued in connection with our audited financial statements for the year ended December 31, 2018 states that there is "substantial doubt about the Company's ability to continue as a going concern." Our ability to continue as a going concern is dependent on a combination of several factors, including, our ability to raise capital by issuing debt or equity securities to investors, license or sell our product candidates to other pharmaceutical companies, and generate revenues from successfully developed products. If we are not able to continue our business as a going concern, we may be forced to liquidate our assets for an amount less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose part or all of their investment.

The Company is currently engaged in litigation with CRG and Dr. Goldberg. In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. Based on our current working capital and our projected cash burn, and without definitive agreements in place for additional funding, management believes that there is substantial doubt about the Company's ability to continue as a going concern for at least twelve months following the issuance of this Annual Report on Form 10-K.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 5,000 square feet of office space at 4995 Bradenton Avenue, Dublin, Ohio, as our principal offices. The current least term expires in June 2020, at a monthly base rent of approximately $3,000. 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 2019, at a monthly base rent of approximately $3,000. We must also pay a pro-rata portion of the electricity costs of the building. We do not intend to renew the lease on the New Jersey office, nor do we currently intend to obtain alternative office space in the New York/New Jersey area. We believe both facilities are in good condition.

We also currently lease approximately 25,000 square feet of office space at 5600 Blazer Parkway, Dublin, Ohio, formerly our principal offices. The current lease term expires in October 2022, at a monthly base rent of approximately $26,000 during 2019. We must also pay a pro-rata portion of the operating expenses and real estate

taxes of the building. In June 2017, the Company executed a sublease arrangement for the Blazer space, providing for monthly sublease payments to Navidea of approximately $39,000 through October 2022.

Item 3. Legal Proceedings

See Note 15 to the accompanying consolidated financial statements.

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 American exchange under the trading symbol "NAVB." As of March 1, 2019, we had approximately 590 holders of common stock of record. There were no repurchases of our common stock during the year ended December 31, 2018.

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, 2013 through December 31, 2018. This graph assumes an investment in the Company's common stock and the indices of $100 on December 31, 2013 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 12/31/2013 in stock or index, including reinvestment of dividends.

	Cumulative Total Return as of December 31,					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Navidea Biopharmaceuticals	$100.00	$91.30	$64.25	$30.92	$17.39	$4.83
Russell 3000	100.00	110.45	108.83	120.16	142.81	132.83
NASDAQ Biotechnology	100.00	134.10	149.42	117.02	141.66	128.45

Item 6. Selected Financial Data

Not applicable to smaller reporting companies.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read together with our Consolidated Financial Statements and the Notes related to those statements, as well as the other financial information included in this Form 10-K. Some of our discussion is forward-looking and involves risks and uncertainties. For information regarding risk factors that could have a material adverse effect on our business, refer to Item 1A of this Form 10-K, "Risk Factors."

The Company

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 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 Tc99m 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.

Other than Tc99m 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.

We manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform and NAV4694 (through the date of sublicensing), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by MT. See Note 18 to the consolidated financial statements for more information about our business segments.

In the near term, the Company intends to continue to develop our additional imaging product candidates into advanced clinical testing with the goal of extending the regulatory approvals for use of the Tc99m 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 our Manocept platform, Tc99m tilmanocept, and NAV4694 product development. We incurred approximately $4.2 million and $4.5 million in total on research and development activities during the years ended December 31, 2018 and 2017, 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 [a]	**2018**	**2017**
Manocept Platform [b]	$1,291,796	$2,140,701
Macrophage Therapeutics [b]	1,203,419	853,294
Tc99m Tilmanocept	145,314	236,004
NAV4694 [c]	19,105	(371,588)

(a) Certain development program expenditures were offset by grant reimbursement revenues totaling $761,000 and $1.7 million during the years ended December 31, 2018 and 2017, respectively.

(b) Certain 2017 amounts have been reclassified from Manocept Platform to Macrophage Therapeutics to conform to 2018 presentation.

(c) Changes in cost estimates resulted in the reversal of certain previously accrued expenses related to the NAV4694 development program during the year ended December 31, 2017.

We expect to continue the advancement of our efforts with our Manocept platform during 2019. The divestiture of NAV4694 has decreased our development costs over the past year. We expect our total research and development expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be higher in 2019 than in 2018.

Tc99m 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. Following the January 2017 transfer of the Tc99m tilmanocept Marketing Authorization to SpePharm, we transferred responsibility for manufacturing the reduced-mass vial for the EU market to SpePharm. During the second quarter of 2017, SpePharm launched Tc99m tilmanocept in select EU markets, providing a number of early adopters with sample doses to provide exposure to the product. EU sales commenced during the third quarter of 2017. We anticipate that we will incur costs related to supporting our product, regulatory, manufacturing and commercial activities related to the potential marketing registration and sale of Tc99m tilmanocept in markets other than the EU. There can be no assurance that Tc99m tilmanocept will achieve regulatory approval in any market other than the EU, or if approved in those markets, that it will achieve market acceptance in the EU or any other market. See Item 1A - “Risk Factors.”

We continue to evaluate existing and emerging data on the potential use of Manocept-related agents in the diagnosis, disease-staging and treatment of disorders in which macrophages are involved, such as RA, KS, NASH 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 of obtaining funding or other resources on terms acceptable to us, if at all, 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 Item 1A - “Risk Factors.”

Discontinued Operations

In March 2017, Navidea completed the Asset Sale to Cardinal Health 414, as discussed previously under “The Company.” 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 $3.0 million of guaranteed earnout payments as part of the CRG settlement, (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, $3.0 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG.

In April 2018, the Company entered into an Amendment to the Asset Purchase Agreement. Pursuant to the Amendment, Cardinal Health 414 paid the Company approximately $6.0 million and agreed to pay the Company an amount equal to the unused portion of the letter of credit (not to exceed approximately $7.1 million) promptly after the earlier of (i) the expiration of the letter of credit and (ii) the receipt by Cardinal Health 414 of evidence of the return

and cancellation of the letter of credit. In exchange, the obligation of Cardinal Health 414 to make any further contingent payments has been eliminated. Cardinal Health 414 is still obligated to make the milestone payments in accordance with the terms of the earnout provisions of the Purchase Agreement. CRG has drawn the entire $7.1 million available under the letter of credit.

We recorded a net gain on the sale of the Business of $89.2 million for the year ended December 31, 2017, including $16.5 million in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by $3.3 million in estimated fair value of warrants issued to Cardinal Health 414, $2.0 million in legal and other fees related to the sale, $800,000 in net balance sheet dispositions and write-offs, and $4.1 million in estimated taxes. We recorded an additional gain related to the Amendment to the Asset Purchase Agreement of $43,000 for the year ended December 31, 2018, including $54,000 of additional consideration, offset by $11,000 in estimated taxes.

Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the Business as a discontinued operation. Cash flows associated with the operation of the Business have been combined with operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows.

Results of Operations

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

Years Ended December 31, 2018 and 2017

Royalty Revenue. During 2018 and 2017, we recognized royalty revenue of $15,000 and $9,000, respectively, related to our license agreement with SpePharm in Europe.

License Revenue. During 2018, we recognized license revenue of $307,000, primarily for a non-refundable upfront payment related to the sublicense of NAV4694 to Meilleur and the sublicense of Tc99m tilmanocept to Sinotau in China. During 2017, we recognized license revenue of $100,000 for a non-refundable upfront payment related to the Tc99m tilmanocept license and distribution agreement with Sayre Therapeutics in India.

Grant and Other Revenue. During 2018, we recognized $847,000 of grant and other revenue compared to $1.7 million in 2017. Grant revenue during 2018 was primarily related to SBIR grants from the NIH supporting Manocept development. Grant revenue during 2017 was primarily related to SBIR grants from the NIH supporting Manocept, therapeutic and Tc99m tilmanocept development. Other revenue for 2018 and 2017 included $85,000 and $31,000, respectively, of revenue primarily from our marketing partners in Europe and China related to development work performed at their request.

Research and Development Expenses. Research and development expenses decreased $292,000, or 6%, to $4.2 million during 2018 from $4.5 million during 2017. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased Manocept development costs of $849,000, primarily decreased clinical trial costs; and (ii) decreased Tc99m tilmanocept development costs of $91,000 including decreased manufacturing-related activities and clinical testing, offset by increased regulatory costs; offset by (iii) increased NAV4694 development costs of $391,000 due to reversal of certain previously accrued expenses during 2017, offset by decreased clinical testing; (iv) increased therapeutics development costs of $350,000, including increased research consulting, regulatory consulting, and preclinical testing, offset by decreased manufacturing-related activities; and (v) increased NAV5001 development costs of $91,000 due to reversal of certain previously accrued expenses during 2017 . The net decrease in research and development expenses also included decreased compensation including incentive-based awards of $309,000 related to net decreased headcount offset by increased general office and travel expenses totaling $124,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $3.5 million, or 31%, to $7.7 million during 2018 from $11.2 million during 2017. The net decrease was primarily due to decreased legal and professional services of $2.7 million primarily related to the CRG litigation, a loss on disposal of assets related to our previous office space of $706,000 and a loss on termination of our previous office lease of $399,000, both during 2017, and decreased general office, insurance, depreciation, rent, and travel expenses totaling $388,000. The net decrease in selling, general and administrative expenses also included net increased compensation expense of $668,000, including termination costs related to the resignation of Dr. Goldberg of $1.1 million in 2018 and termination costs related to the arbitration award to Mr. Gonzalez of $478,000 in 2017.

Other Income (Expense). Other expense, net, was $5.3 million during 2018 compared to other expense, net of $3.9 million during 2017. We recorded losses on extinguishment of the CRG debt of $5.3 million and $4.2 million during 2018 and 2017, respectively. Also during 2018 and 2017, we recognized interest income of $131,000 and $328,000, respectively, primarily related to the guaranteed consideration due from Cardinal Health 414, which was discounted to present value at the closing date of the Asset Sale in 2017. During 2018 and 2017, $153,000 and $265,000, respectively, of interest expense was compounded and added to the balance of our note payable to Platinum. During 2017, we recorded non-cash income of $153,000 related to changes in the estimated fair value of financial instruments.

Gain on Discontinued Operations. We recorded a net gain related to the Amendment to the sale of the Business to Cardinal Health 414 of $43,000 in 2018, including $54,000 of payments by Cardinal Health 414 to Navidea in excess of receivables recognized, offset by $11,000 in estimated taxes. We recorded a net gain on the sale of the Business to Cardinal Health 414 of $89.2 million in 2017, including $16.5 million in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by $3.3 million in estimated fair value of warrants issued to Cardinal Health 414, $2.0 million in legal and other fees related to the sale, $800,000 in net balance sheet dispositions and write-offs, and $4.1 million in estimated taxes. Operating income (loss) from discontinued operations related to the sale of the Business to Cardinal Health 414 were $1,000 and ($491,000) for 2018 and 2017, respectively.

Liquidity and Capital Resources

Cash balances increased $681,000 to $3.5 million at December 31, 2018 from $2.8 million at December 31, 2017. The net increase was primarily due to accelerated receipt of the guaranteed earnout receivable from Cardinal Health 414 of $5.7 million, net of CRG’s draw on the letter of credit of $7.2 million, proceeds from a private equity placement of $3.0 million, and maturities and sales of available-for-sale securities of $1.6 million, offset by cash used to fund our operations of $1.5 million.

Operating Activities. Cash provided by operations was $4.3 million during 2018 compared to $59.1 million during 2017.

Accounts and other receivables decreased $8.1 million to $21,000 at December 31, 2018 from $8.1 million at December 31, 2017, primarily related to Cardinal Health 414’s payment of the entire balance of the guaranteed earnout of $12.9 million pursuant to the Amendment executed on April 2, 2018.

Prepaid expenses and other current assets increased $198,000 to $1.3 million at December 31, 2018 from $1.1 million at December 31, 2017. The increase was primarily due to a net increase in federal and state tax refunds receivable, offset by a net decrease in prepaid insurance and decreased interest receivable related to the guaranteed earnout due from Cardinal Health 414.

Accounts payable decreased $430,000 to $425,000 at December 31, 2018 from $855,000 at December 31, 2017, primarily driven by net decreased payables due to operations, NAV4694 and therapeutics vendors, offset by increased payables due to Manocept development vendors. Accrued liabilities and other current liabilities increased $663,000 to $2.5 million at December 31, 2018 from $1.9 million at December 31, 2017. Increased accruals for termination of Dr. Goldberg and Manocept development vendors were offset by decreases in accruals for incentive-based compensation, legal and professional services. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we work to resolve our legal disputes, offset by planned increases in development activity related to the Manocept platform.

Investing Activities. Investing activities provided $954,000 during 2018 compared to $1.8 million used during 2017. Investing activities during 2018 included maturities and sales of available-for-sale securities of $1.6 million, purchases of available-for-sale securities of $600,000, and capital expenditures of $46,000, primarily for research and computer equipment. Investing activities during 2017 included purchases of available-for-sale securities of $2.2 million and capital expenditures of $34,000, primarily for computer equipment and leasehold improvements, offset by maturities of available-for-sale securities of $400,000. We expect our overall capital expenditures for 2019 will be higher than 2018 as we work to increase our manufacturing efficiency and maintain our technology infrastructure.

Financing Activities. Financing activities used $4.5 million during 2018 compared to $61.0 million during 2017. The $4.5 million used by financing activities during 2018 consisted primarily of CRG’s draw on the letter of credit of $7.1 million and principal payments on financed insurance premiums of $396,000, offset by proceeds from a private equity placement of $3.0 million. The $61.0 million used by financing activities in 2017 consisted primarily of principal payments on the CRG, Platinum and IPFS notes payable of $59.8 million and payment of debt-related costs of $1.3 million, offset by proceeds from issuance of common stock of $72,000.

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. 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.

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 $3.0 million of guaranteed earnout payments as part of the CRG settlement, (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, $3.0 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG.

We recorded a net gain on the sale of the Business of $89.2 million for the year ended December 31, 2017, including $16.5 in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by $3.3 million in estimated fair value of warrants issued to Cardinal Health 414, $2.0 million in legal and other fees related to the sale, $800,000 in net balance sheet dispositions and write-offs, and $4.1 million in estimated taxes. The guaranteed consideration was recorded as a receivable, the balance of which was being reduced as quarterly payments were received.

On April 2, 2018, the Company entered into an Amendment to the Asset Purchase Agreement. Pursuant to the Amendment, Cardinal Health 414 paid the Company approximately $6.0 million and agreed to pay the Company an amount equal to the unused portion of the letter of credit (not to exceed approximately $7.1 million) promptly after the earlier of (i) the expiration of the letter of credit and (ii) the receipt by Cardinal Health 414 of evidence of the return and cancellation of the letter of credit. In exchange, the obligation of Cardinal Health 414 to make any further contingent payments has been eliminated. Cardinal Health 414 is still obligated to make the milestone payments in accordance with the terms of the earnout provisions of the Purchase Agreement. We recorded an additional gain related to the Amendment to the Asset Purchase Agreement of $43,000 for the year ended December 31, 2018, including $54,000 of additional consideration, offset by $11,000 in estimated taxes. On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit. See Note 3 to the accompanying consolidated financial statements.

Private Placement

On September 13, 2018, the Company entered into a Stock Purchase Agreement with an investor, pursuant to which the Company issued 18,320,610 shares of the Company's common stock in exchange for $3.0 million in cash. The Company plans to use the proceeds from the Private Placement for general working capital purposes, including, without limitation, research and development, and other operating expenses. See Notes 2 and 16(a) to the accompanying consolidated financial statements.

Capital Royalty Group Debt

See Notes 2, 12 and 15 to the accompanying consolidated financial statements.

Platinum Credit Facility

See Notes 2, 12 and 15 to the accompanying consolidated financial statements.

Summary

Our future liquidity and capital requirements will depend on a number of factors, including the ability of our distribution partners 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.

We plan to focus our resources in 2019 primarily on development of products based on the Manocept platform. Although management believes that it will be able to achieve this objective, it is subject to a number of variables beyond our control, including 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 financing if we cannot achieve that objective in a timely manner.

We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. If we attempt to raise additional capital through debt, royalty, equity or otherwise, we may not be successful in doing so on terms acceptable to the Company, if at all. Further, we may not be able to gain access and/or be able to secure new sources of funding, identify 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.

The Company is currently engaged in litigation with CRG and Dr. Goldberg. In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. We have considerable discretion over the extent of development project expenditures and have the ability to curtail the related cash flows as needed. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of funding, including collaborations, potential equity investments, and additional grant funding that can augment the balance sheet. However, based on our current working capital and our projected cash burn, and without definitive agreements in place for additional funding, management believes that there is substantial doubt about the Company's ability to continue as a going concern for at least twelve months following the issuance of this Annual Report on Form 10-K. See Note 2 to the accompanying consolidated financial statements and Item 1A – "Risk Factors."

Off-Balance Sheet Arrangements

As of December 31, 2018, we had no off-balance sheet arrangements.

Recent Accounting Standards

See Notes 1(q) and 1(r) to the accompanying consolidated financial statements.

Critical Accounting Policies

Revenue Recognition. We currently generate revenue primarily from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been paid and payments under the grants become contractually due.

We also earn revenues related to our licensing and distribution agreements. The consideration we are eligible to receive under our licensing and distribution agreements typically includes upfront payments, reimbursement for research and development costs, milestone payments, and royalties. Each licensing and distribution agreement is unique and requires separate assessment in accordance with current accounting standards.

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 U.S. GAAP 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, subject to an estimated forfeiture rate. The fair value of each option award with time-based vesting provisions is estimated on the date of grant using the Black-Scholes option pricing model to value such stock-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. The fair value of each option award with market-based vesting provisions is estimated on the date of grant using a Monte Carlo simulation to value such stock-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 a Monte Carlo simulation 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. 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.

Fair Value of Financial Instruments. Certain of our notes payable included an embedded conversion option which was required to be recorded at fair value. The estimated fair value of the embedded conversion option was calculated using a probability-weighted Monte Carlo simulation. This valuation method includes 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 embedded conversion option are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations.

Fair Value of Warrants. We estimate the fair value of warrants using the Black-Scholes model, which is affected by our stock price and warrant exercise price, as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility and risk-free interest rate.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to smaller reporting companies.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, and the related notes, together with the report of Marcum LLP dated March 15, 2019, are set forth at pages F-1 through F-36 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 Mr. Latkin, who serves as our Chief Executive Officer, 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, 2018, and concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report to ensure that information required to be disclosed by us in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. 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.

Our management, including Mr. Latkin, who serves as our Chief Executive Officer, 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 U.S. GAAP 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 Mr. Latkin, who serves as our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based upon the criteria set forth in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). Based on our assessment we concluded that, as of December 31, 2018, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control Over Financial Reporting

During the year ended December 31, 2018, 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.

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)
Claudine Bruck, Ph.D. [(a)]	63	Audit; Compensation, Nominating and Governance (Chair)
Adam D. Cutler [(b)]	44	Audit (Chair); Compensation, Nominating and Governance
Jed. A. Latkin [(c)]	44	—
Y. Michael Rice	54	Audit; Compensation, Nominating and Governance
S. Kathryn Rouan, Ph.D. [(d)]	56	Compensation, Nominating and Governance

(a) Dr. Bruck was appointed to the Board of Directors effective March 5, 2018.
(b) Mr. Cutler was appointed to the Board of Directors effective December 1, 2018.
(c) Mr. Latkin was appointed to the Board of Directors effective August 14, 2018.
(d) Dr. Rouan was appointed to the Board of Directors effective December 1, 2018.

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 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 ("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 2019 Annual Meeting:

Y. Michael Rice has served as a director of Navidea since May 2016. Mr. Rice is a 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 Bank 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.

S. Kathryn Rouan, Ph.D., has served as a director of Navidea since December 2018. Dr. Rouan most recently served as the SVP and Head of Projects, Clinical Platforms and Sciences ("PCPS") at GlaxoSmithKline ("GSK") from May 2016 to November 2018 following a 29-year career at GSK. The PCPS organization within GSK encompasses the Global Clinical Operations, Statistics and Programming, Clinical Pharmacology, GCP Quality, Third Party Resourcing and Project Management functions and includes approximately 1,800 staff in 20 countries. Dr. Rouan first joined GSK in 1989 with a background in Pharmaceutical Sciences, focusing on formulation development of protein pharmaceuticals. In 1993, Dr. Rouan moved into Project Leadership and Management becoming VP and Head of Metabolism and Pulmonary Project Management in 1999. She continued to lead Projects in a number of Therapeutic areas including Cardiovascular, Immunoinflammation and Gastroenterology Therapy areas. In 2007, Dr. Rouan led the development, submission and approval of Arzerra (ofatumumab) in refractory chronic lymphocytic leukemia. In 2012, she became Head of Biopharmaceutical Development responsible for delivery of GSK's portfolio of biopharmaceutical medicines. In December 2013, Dr. Rouan was appointed SVP and Head of R&D Stiefel, GSK's Dermatology therapy area unit. Dr. Rouan holds a Ph.D. in Pharmaceutical Sciences from the University of Rhode Island, and a B.Pharm. from the University of London.

Directors whose terms continue until the 2020 Annual Meeting:

Adam D. Cutler has served as a director of Navidea since December 2018. Mr. Cutler is a biotechnology executive with over 20 years of experience in equity research, investor relations, capital markets, business development, finance, and management consulting. Mr. Cutler joined Molecular Templates, Inc. as its Chief Financial Officer in November 2017. Prior to that, he was Senior Vice President of Corporate Affairs for Arbutus Biopharma Corporation, where he was responsible for investor relations and contributed to the company's business development and corporate finance efforts from March 2015 to November 2017. From 2012 to 2015, he was a Managing Director for The Trout Group LLC and Trout Capital LLC, where he executed financings and advised public and private life science companies on investor relations and capital raising strategies. From 2000 to 2012, Mr. Cutler worked as a biotechnology equity research analyst with Credit Suisse, Canaccord Genuity, JMP Securities, and Bank of America Securities. He also worked in healthcare consulting as an Analyst at The Frankel Group and a Consultant for Ernst & Young LLP. He currently serves on the Board of Directors for Inmed Pharmaceuticals. He earned his Bachelor of Arts degree in

Economics from Brandeis University.

Jed A. Latkin has served as Chief Executive Officer of Navidea since October 2018, and as Chief Operating Officer and Chief Financial Officer of Navidea since May 2017. Mr. Latkin also served as Interim Chief Operating Officer of Navidea from April 2016 to April 2017. 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 served 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.

Director whose term continues until the 2021 Annual Meeting:

Claudine Bruck, Ph.D., has served as a director of Navidea since March 2018. Dr. Bruck is co-founder and has served as Chief Executive Officer of Prolifagen LLC, a start-up company developing a microRNA-based medicine for tissue regeneration, since June 2016. She is also a course director at University of Pennsylvania's Institute of Translational Medicine and Applied Technology, a consultant to BioMotiv LLC and a member of the board of directors of QRPharma, a biotechnology company focused on development of medicines for neurodegenerative diseases. Dr. Bruck joined GlaxoSmithKline ("GSK") to build GSK's HIV vaccine program in 1985. In her role in GSK's vaccine group, Dr. Bruck was instrumental in the development of GSK's HPV vaccine (Cervarix), and headed their cancer vaccine program from inception to Phase 2 before joining the drug discovery group of GSK. She held several roles in the drug discovery group, from Head of Clinical Immunology (2004-2005) to VP and Head of Biology for the Center of Excellence for External Drug Discovery (2005-2008), to VP and Head of a newly formed ophthalmology R&D group (2008-2015). Dr. Bruck has a Ph.D. in Biochemistry from the University of Brussels. She was a post-doctoral student at Harvard University Medical School and an Assistant Professor at Tufts Medical School.

Directors whose terms ended during 2018:

Michael M. Goldberg, M.D. served as a director of Navidea from November 2013 to August 2018 and as President and Chief Executive Officer of Navidea from September 2016 to August 2018. 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 served as a director of Navidea from March 2016 to August 2018. 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 1987-2009 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 previously served as a scientific advisor to Navidea's subsidiary, Macrophage Therapeutics, Inc., 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 Ribi Immunochem Research, Inc. and currently serves as a Consultant to Martell Biosystems, Inc. Dr. Greene also serves as an advisor to Belgene, SternGreene and Abzed, all start-up companies. 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 1976 and then joined the faculty of Harvard Medical School in 1976.

Eric K. Rowinsky, M.D. served as a director of Navidea from July 2010 to March 2018. Dr. Rowinsky has served as Executive Chairman, President, and Head of the Scientific Advisory Board of RGenix, Inc, as well as the Chief Scientific Officer of Clearpath Development Co., which rapidly advances development stage therapeutic assets to pre-defined human Proof-of-Concept milestones, since June 2015. He has also served as the Head of Research and Development, Executive Vice President, and Chief Medical Officer of Stemline Therapeutics, Inc. from 2012 to 2015, and was the Founder of and served as Chief Executive Officer of Primrose Therapeutics from August 2010 to September 2011 at which time it was acquired by Stemline. 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., Verastem, Inc. and Fortress Biotech, Inc., and has served on the board of directors of BIND Therapeutics, Inc., all publicly-held life science 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 Mr. Latkin, the following individual is a senior executive officer of Navidea and serves in the position indicated below:

Name	Age	Position
Michael S. Rosol, Ph.D.	50	Chief Medical Officer

Michael S. Rosol, Ph.D., has served as Chief Medical Officer of Navidea since December 2018. Prior to joining Navidea, Dr. Rosol served as Associate Director in the Clinical and Translational Imaging Group at Novartis Institutes for BioMedical Research from November 2016 to December 2018. Before that, he held positions as Senior Director of Business Development at Elucid Bioimaging, Inc. where he drove adoption of its Computer-Aided Phenotyping applications from May 2016 to November 2016, and as Chief Scientific Officer of MediLumine, Inc. from October 2015 to May 2016. Prior to those roles, he was the Head of the Translational Imaging Group at Novartis Pharmaceuticals Group from October 2012 to March 2015. His training and experience lie in the fields of biophysics, physiology, and biological/medical imaging, and his work has focused on cardiovascular imaging, preclinical and clinical imaging instrumentation and applications, animal models of human disease, pathophysiology, biomarkers, and imaging in toxicological and clinical trials. He has also served as faculty in Radiology and Director of two academic research imaging facilities. Dr. Rosol holds a Ph.D. from Boston University School of Medicine.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act 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, 2018, except for: (1) Frederick O. Cope, Ph.D., who had one late Form 4 filing related to stock issued in lieu of a portion of his annual cash bonus; (2) John K. Scott, Jr., who had one late Form 3 filing related to stock purchased in a private placement; (3) S. Kathryn Rouan, Ph.D., who had one late Form 3 filing resulting from delays in obtaining new EDGAR filer codes; and (4) Michael M. Goldberg, M.D., who did not file a Form 4 related to the 18.5 million shares issued to him in November 2018. Dr. Goldberg was no longer an officer or director of Navidea at the time the 18.5 million shares were issued to him.

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, 4995 Bradenton Avenue, Suite 240, 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 seven meetings in the fiscal year ended December 31, 2018, 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 or she served, except for Dr. Rowinsky. 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 2018 Annual Meeting of Stockholders in person.

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 current members of our Audit Committee are: Adam D. Cutler (Chair), Claudine Bruck, Ph.D., and Y. Michael Rice, each of whom is “independent” under Section 803A of the NYSE American Company Guide. From August 14, 2018 through January 1, 2019, the members of our Audit Committee were: Mr. Rice (Chair) and Dr. Bruck. From March 15, 2018 to August 14, 2018, the members of our Audit Committee were: Mr. Rice (Chair), Dr. Bruck and Dr. Greene. From January 1, 2018 to March 15, 2018, the members of our Audit Committee were: Mr. Rice (Chair), Dr. Greene and Dr. Rowinsky. The Board of Directors has determined that Mr. Cutler and Mr. Rice meet 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 four meetings in the fiscal year ended December 31, 2018. 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: Claudine Bruck, Ph.D. (Chair), Adam D. Cutler, Y. Michael Rice, and S. Kathryn Rouan, Ph.D. The CNG Committee did not hold any meetings in the fiscal year ended December 31, 2018 because compensation- and nomination-related discussions were 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 maintain compensation plans that are fair, reasonable and competitive. The CNG Committee is responsible for reviewing and approving senior executive compensation, 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 toward 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 assess whether our programs are competitive, the CNG Committee reviews compensation information of peer companies, national data and trends in executive compensation to help determine the appropriateness of our plans and compensation levels. These reviews, and the CNG Committee's commitment to pay for performance, become the basis for the CNG Committee's decisions on compensation plans and individual executive compensation payments.

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

Reward executives based upon overall company performance, their individual contributions and creation of stockholder value;

Encourage 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 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?

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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 has historically been tied to Company financial performance (e.g., revenue, gross margin or budgeted expense targets) or product development goals (e.g., clinical trial progress or regulatory milestones). Following the Asset Sale to Cardinal Health 414 in March 2017, incentive-based compensation goals have been more focused on development goals as we work to develop additional product candidates. The CNG Committee believes that the existence of these performance incentives creates a strong motivation for Company employees to contribute towards the achievement of strong, sustainable 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 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 June 29, 2017, approximately 75% 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. The CNG Committee will continue to consider the results of future say-on-pay votes when making future compensation decisions for the executive officers. Also at the Annual Meeting of Stockholders on June 29, 2017, approximately 40% of our stockholders, representing the most votes received, voted in favor of holding "say-on-pay" votes every two years. In accordance with the results of this vote, the Company will hold an advisory vote to approve the compensation of the Company's Named Executive Officers every two years until the next required vote on the frequency of advisory votes on executive compensation at the Company's Annual Meeting of Stockholders to be held in 2023.

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 periodically 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 Board Advisory, LLC ("Board Advisory") as its independent consultant to assist in the determination of the reasonableness and competitiveness of the compensation levels of its President and Chief Executive Officer for fiscal 2018, and of its Chief Executive Officer, Chief Operating Officer, and Chief Financial Officer, Chief Medical Officer, and Board of Directors for fiscal 2019. No conflict of interest exists that would prevent Board Advisory from serving as independent consultant to the CNG Committee.

For fiscal 2018, Board Advisory performed a benchmark compensation review of our President and Chief Executive Officer. For fiscal 2019, Board Advisory performed a benchmark compensation review of our key executive positions, including our Chief Executive Officer, Chief Operating Officer, and Chief Financial Officer, Chief Medical Officer, and our Board of Directors. Board Advisory utilized published survey and proxy reported data from compensation peers, with market data aged to February 1, 2018 and January 1, 2019, respectively, by an annualized rate of 3.0%, the expected pay increase in both 2018 and 2019 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 Board Advisory study for 2019, the CNG Committee noted that the total cash compensation of our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer is between the 50th and 75th percentile for an established peer group of companies. The CNG Committee also noted that the total cash compensation of our Chief Medical Officer is significantly below the market rate for this position.

Peer Group Companies. In addition to independent survey analysis, in 2018 and 2019 the CNG Committee reviewed the compensation levels at specific competitive benchmark companies. With input from management, the CNG Committee chose the peer companies because they are developmental life sciences companies, have market capitalization between approximately $20 million and $350 million and 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:

AcelRx Pharmaceuticals, Inc.	Idera Pharmaceuticals, Inc.
Anthera Pharmaceuticals, Inc.	Immune Design Corporation
Aradigm Corporation	Innovation Pharmaceuticals, Inc.
Argos Therapeutics, Inc.	Invitae Corporation
CareDx, Inc.	Invuity, Inc.
Cascadian Therapeutics, Inc.	Lipocine, Inc.
ContraFect Corporation	Mirati Therapeutics, Inc.
Curis, Inc.	Sonoma Pharmaceuticals, Inc.
CytoDyn, Inc.	Sorrento Therapeutics, Inc.
Endocyte, Inc.	T2 Biosystems, Inc.
Genocea Biosciences, Inc.	Utah Medical Products, Inc.
iCad, Inc.	

Board Advisory 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 Board Advisory, peer company data, national surveys, general compensation trend information and recommendations from management, the CNG Committee approved the fiscal 2018 base salary for our President and Chief Executive Officer. 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 2018, the CNG Committee considered published proxy data for similar positions at peer group companies.

The following table shows the changes in base salaries for the Named Executive Officers that were approved for fiscal 2018 compared to the approved salaries for fiscal 2017:

Named Executive Officer	Fiscal 2018 Base Salary[a]	Fiscal 2017 Base Salary[a]	Change[b]	
Jed A. Latkin [c]	$475,000	$325,000	46.2	%
Michael M. Goldberg, M.D. [d]	400,000	400,000	0.0	%
Frederick O. Cope, Ph.D. [e]	279,130	279,130	0.0	%
Michael S. Rosol, Ph.D. [f]	205,000	—	—	

(a) The amount shown for fiscal 2018 and 2017 is the approved annual salary of the Named Executive Officer in effect at the end of each year, or at the date of separation. The actual amount paid to the Named Executive Officer during fiscal 2018 and 2017 is shown under “Salary” in the Summary Compensation table below.

(b) Due to the Company’s financial difficulties in 2018, Named Executive Officers did not receive salary increases in 2018, except for Mr. Latkin.

(c) Mr. Latkin received an increase in base salary in connection with his appointment as Chief Executive Officer, Chief Operating Officer and Chief Financial Officer of the Company effective October 1, 2018.

(d) Dr. Goldberg separated from the Company effective August 14, 2018.

(e) Dr. Cope separated from the Company effective October 30, 2018.

(f) Dr. Rosol commenced employment with the Company effective December 17, 2018.

The following table shows the base salaries for the Named Executive Officers that were approved for fiscal 2019 compared to the approved salaries for fiscal 2018:

Named Executive Officer	Fiscal 2019 Base Salary	Fiscal 2018 Base Salary	Change[(a)]	
Jed A. Latkin	$475,000	$475,000	0.0	%
Michael S. Rosol, Ph.D.	205,000	205,000	0.0	%

(a) Due to Mr. Latkin's recent promotion and Dr. Rosol's recent hiring, they did not receive salary increases in 2019.

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, except interns.

The CNG Committee is responsible for specifying the terms and conditions for earning cash bonuses, including establishing specific performance objectives.

As soon as reasonably practicable after the end of each fiscal year, the CNG Committee determines whether and to what extent each specified business performance objective has been achieved and the amount of the cash bonus to be paid to each participant.

In June 2018, the Board of Directors established the fiscal 2018 targets and performance measures for all Company employees. For fiscal 2018, the cash bonus for each executive officer was a function of the designated target bonus amount and certain business performance objectives, weighted as a percentage of the total target amount. The business performance objectives established for fiscal 2018 were as follows:

Achievement of various development goals for diagnostic applications of the Company's Manocept platform, subject to a maximum 75% reduction of bonus if not achieved, including:

- Complete the Company's IV dosing study for RA;
- Complete the Company's IV dosing study for NASH;
- Initiate an IV dosing study for CV; and
- Complete a development plan for imaging active M1-mediated inflammation, RA diagnosis and/or monitoring.

Achievement of various development goals for therapeutic applications of the Company's Manocept platform, subject to a maximum 15% reduction of bonus if not achieved, including:

- Complete a development plan for treating active M1-mediated inflammation, demonstration for potential partners for systemic applications;
- Complete a development plan for an orphan disease indication;
- Complete animal testing by two corporate entities for possible partnering; and
- Pursue new backbone efforts – lower molecular weight, new polymer with range of molecular weights.

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Achievement of various development goals for new formulations, subject to a maximum 10% reduction of bonus if not achieved, including:

- Get a lab up and running, all equipment acquired and on-site;
- Pursue topical as well as oral formulations with new lower molecular weight agents; and
- Develop a new isotope for PET imaging and fluorescent probe for next generation.

For fiscal 2018, the Board of Directors determined the cash bonus targets for Named Executive Officers as follows:

Named Executive Officer	Target Cash Bonus (% of Salary)		Target Cash Bonus ($ Amount)
Jed A. Latkin [(a)]	75.0	%	$ 356,250
Michael M. Goldberg, M.D. [(b)]	75.0	%	300,000
Frederick O. Cope, Ph.D. [(c)]	35.0	%	97,696
Michael S. Rosol, Ph.D. [(d)]	35.0	%	71,750

(a) Mr. Latkin was promoted to Chief Executive Officer effective October 1, 2018. Any cash bonus awarded to Mr. Latkin related to fiscal 2018 will be pro-rated based on the weighted average amount of his base salary during 2018.

(b) Dr. Goldberg separated from the Company effective August 14, 2018. Any bonus awarded for fiscal 2018 will be paid to Dr. Goldberg in accordance with his termination agreement. Additional information regarding Dr. Goldberg's termination agreement, dated August 14, 2018, is disclosed in "Post-Employment Compensation," below.

(c) Dr. Cope separated from the Company effective October 30, 2018 and therefore will not be paid a bonus for fiscal 2018.

(d) Dr. Rosol commenced employment with the Company effective December 17, 2018. Any bonus awarded for fiscal 2018 will be pro-rated from Dr. Rosol's effective date of employment.

On February 7, 2019, the Board of Directors determined the amounts to be awarded as 2018 bonuses to all employees, including the Named Executive Officers. The Board of Directors recognized the achievement of all 2018 bonus goals and thus awarded bonuses at 100% of target amounts for all employees.

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.

Equity-based compensation is an effective method to align the interests of stockholders and management and focus management's attention on long-term results. When awarding equity-based compensation the CNG Committee considers the impact the participant can have on our overall performance, strategic direction, financial results and stockholder value. Therefore, equity awards are primarily based upon the participant's position in the organization, competitive necessity and individual performance. Stock option awards have vesting schedules over several years to promote long-term performance and retention of the recipient, and restricted stock awards may include specific performance criteria for vesting or vest over a specified period of time. We did not grant equity awards to our Named Executive Officers in 2018.

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 paid time off ("PTO") policy allows employees to carry up to 40 hours of unused PTO time forward to the next fiscal year. Any unused PTO time in excess of the amount eligible for rollover is generally forfeited.

Our Named Executive Officers are considered "key employees" for purposes of Internal Revenue Code ("IRC") Section 125 Plan non-discrimination testing. Based on such non-discrimination testing, we determined that our Section 125 Plan was "top-heavy" for fiscal 2017. Accordingly, our key employees were ineligible to participate in the Section 125 Plan and were unable to pay their portion of medical, dental, and vision premiums on a pre-tax basis during fiscal 2017. As a result, the Company reimbursed its key employees an amount equal to the lost tax benefit. For fiscal 2018, we have determined that our Section 125 Plan is no longer "top-heavy." Accordingly, our key employees are eligible to participate in the Section 125 Plan and may pay their portion of medical, dental and vision premiums on a pre-tax basis beginning January 1, 2018.

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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 $400,000.

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

Jed A. Latkin. Mr. Latkin is employed under a 24-month employment agreement effective through September 30, 2020. The employment agreement provides for an annual base salary of $475,000. For the calendar year ending December 31, 2018, the CNG Committee determined that the maximum bonus payment to Mr. Latkin would be $356,250.

Mr. Latkin's employment agreement also provides for post-employment compensation based on the reason for termination:

For Cause – All salary, benefits and other payments shall cease at the time of termination, and the Company shall have no further obligations to Mr. Latkin.

Resignation – All salary, benefits and other payments shall cease at the time of termination, and the Company shall have no further obligations to Mr. Latkin, except that the Company shall pay the value of any accrued but unused PTO, and the amount of all accrued but previously unpaid salary through the date of termination.

Death – All salary, benefits and other payments shall cease at the time of death, provided, however, that the Company shall pay such other benefits required to be paid or provided to Mr. Latkin's estate under any plan, program, policy, practice, contract, or arrangement in which Mr. Latkin is eligible to receive such payments or benefits from the Company, for the longer of 12 months or the full unexpired term of the employment agreement. The Company shall also pay to Mr. Latkin's estate the value of any accrued but unused PTO and the amount of any accrued but previously unpaid salary through the date of death.

Disability – All salary, benefits and other payments shall cease at the time of termination due to disability, provided, however, that the Company shall pay such other benefits required to be paid or provided to Mr. Latkin under any plan, program, policy, practice, contract, or arrangement in which Mr. Latkin is eligible to receive such payments or benefits from the Company, for the longer of 12 months or the full unexpired term of the employment agreement. In addition, the Company will pay the balance of Mr. Latkin's regular salary not replaced by disability insurance coverage for six months following the date of disability. The Company shall also pay to Mr. Latkin the value of any accrued but unused PTO and the amount of any accrued but previously unpaid salary through the date of such termination.

Without Cause or by Mr. Latkin for Good Reason – The Company shall pay the value of any accrued but unused PTO, and the amount of all accrued but previously unpaid salary through the date of termination. In addition, the Company will pay a severance equal to base salary in effect at the time of termination during the period of time from the date of termination through the date that is 12 months following termination, plus an additional two months for every fully completed year of employment (the "Severance Period"). The Company will also pay the unpaid bonus, if any, for the year in which the termination occurs, prorated to the date of termination. In addition, certain share options shall vest immediately and shall be exercisable for the Severance Period (but not beyond the original expiration date). The Company will also pay such other benefits required to be paid or provided to Mr. Latkin under any plan, program, policy, practice, contract, or arrangement in which Mr. Latkin is eligible to receive such payments or benefits from the Company, for the duration of the Severance Period.

End of Term – The Company shall pay the value of any accrued but unused PTO, and the amount of all accrued but previously unpaid salary through the date of termination.

Change in Control – The Company will pay a severance equal to: (1) base salary in effect at the time of termination during the Severance Period; (2) a bonus equal to one year of base salary in effect at the time of termination, plus an additional two months of base salary for every fully completed year of employment and a bonus equal to the maximum allowable bonus in effect at the time of termination, plus an additional two months of prorated bonus for every fully completed year of employment; and (3) without duplication to (2), the unpaid bonus, if any, for the year in which the termination occurs, prorated to the date of termination. In addition, certain share options shall vest immediately.

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

Claudine Bruck, Ph.D. (Chair)
Adam D. Cutler
Y. Michael Rice
S. Kathryn Rouan, Ph.D.

Compensation, Nominating and Governance Committee Interlocks and Insider Participation

The current members of our CNG Committee are: Claudine Bruck, Ph.D. (Chair), Adam D. Cutler, Y. Michael Rice, and S. Kathryn Rouan, Ph.D. None of these individuals were at any time during the fiscal year ended December 31, 2018, or at any other time, an officer or employee of the Company.

No director who served on the CNG Committee during 2018 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 2018.

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 2018

Named Executive Officer	Year	Salary	Stock Awards	(a) Option Awards	(b) Non-Equity Incentive Plan Compensation	(c) All Other Compensation	Total Compensation
Jed A. Latkin [d]	2018	$362,500	$ —	$—	$ 271,875	$ 5,500	$ 639,875
Chief Executive Officer,	2017	316,458	—	125,833	366,653	5,429	814,373
Chief Operating Officer and Chief Financial Officer	2016	163,309	—	39,992	—	—	203,301
Michael M. Goldberg [e]	2018	$250,000	$ —	$—	$ 225,000	$ 1,017,722	$ 1,492,722
President and	2017	427,222	—	—	410,768	8,067	846,057
Chief Executive Officer	2016	83,077	—	—	—	436	83,513
Frederick O. Cope, Ph.D. [f]	2018	$242,409	$ —	$—	$ —	$ 5,500	$ 247,909
Senior Vice President and	2017	279,130	—	—	97,969	6,906	383,732
Chief Scientific Officer	2016	279,130	—	—	54,710	6,735	340,575
Michael S. Rosol, Ph.D. [g]	2018	$8,542	$ —	$—	$ 2,949	$ —	$ 11,491
Chief Medical Officer	2017	—	—	—	—	—	—
	2016	—	—	—	—	—	—

(a) Amount represents the aggregate grant date fair value of stock options 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.

(b) 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).

On April 25, 2017, the Board of Directors awarded a cash bonus to each of Dr. Goldberg and Mr. Latkin in recognition of the successful closing of the Company's sale of certain assets to Cardinal Health 414, LLC, which

occurred on March 3, 2017.

On February 20, 2018, the Board of Directors determined that fifty percent of the 2017 bonus amount payable would be paid in stock in lieu of cash for all employees except Dr. Goldberg and Mr. Latkin, who will receive one hundred percent of their bonuses in cash, to be paid following achievement of certain additional goals set by the Board. As such, Dr. Cope was awarded 135,694 shares of common stock of the Company valued at $0.36 per share, the closing price of Navidea's common stock on February 20, 2018. On June 29, 2018, the Board of Directors determined that the remaining fifty percent of the 2017 bonus amount payable would be paid in stock in lieu of cash for all employees except Dr. Goldberg and Mr. Latkin. As such, Dr. Cope was awarded 212,390 shares of common stock of the Company valued at $0.23 per share, the closing price of Navidea's common stock on June 29, 2018. Since these shares represent incentive compensation earned in 2017, they are reported in this column, and not included in the column "Stock Awards."

For fiscal 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 did not award bonuses to Dr. Goldberg and Mr. Latkin for 2016.

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

(d) Mr. Latkin commenced employment with the Company effective April 21, 2016.

(e) Dr. Goldberg commenced employment with the Company effective September 22, 2016, and separated from the Company effective August 14, 2018. Additional information regarding Dr. Goldberg's termination agreement, dated August 14, 2018, is disclosed in "Post-Employment Compensation," below.

(f) Dr. Cope separated from the Company effective October 30, 2018.

(g) Dr. Rosol commenced employment with the Company effective December 17, 2018.

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 2018

Named Executive Officer	Year	Severance	(a) Reimbursement of Additional Tax Liability Related to Insurance Premiums	(b) 401(k) Plan Employer Matching Contribution	Total All Other Compensation
Jed A. Latkin	2018	$—	$ —	$ 5,500	$ 5,500
	2017	—	29	5,400	5,429
	2016	—	—	—	—
Michael M. Goldberg, M.D. (c)	2018	$1,012,552	$ —	$ 5,170	$ 1,017,722
	2017	—	2,667	5,400	8,067
	2016	—	436	—	436
Frederick O. Cope, Ph.D.	2018	$—	$ —	$ 5,500	$ 5,500
	2017	—	1,506	5,400	6,906
	2016	—	1,435	5,300	6,735
Michael S. Rosol, Ph.D.	2018	$—	$ —	$ —	$ —
	2017	—	—	—	—
	2016	—	—	—	—

(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 accrued for contribution to the Named Executive Officer's account in our 401(k) Plan as calculated on a quarterly basis.

(c)

Dr. Goldberg separated from the Company effective August 14, 2018. Severance amount includes $978,000 of severance plus $34,552 representing payment for 16 months of insurance premiums, in accordance with his termination agreement. Additional information regarding Dr. Goldberg's termination agreement, dated August 14, 2018, is disclosed in "Post-Employment Compensation," below.

Chief Executive Officer Pay Ratio

As required by Section 953(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and Item 402(u) of Regulation S-K, we are providing the following information with respect to our last completed fiscal year. The pay ratio information provided below is a reasonable estimate calculated in a manner consistent with applicable SEC rules.

For 2018, we calculated (i) the annual total compensation of our Chief Executive Officer, (ii) the median of the annual total compensation of all of our employees other than the Chief Executive Officer, and (iii) the ratio of the annual total compensation of our Chief Executive Officer to the median of the annual total compensation of all other employees, as follows:

- The annual total compensation of our CEO, as reported in the Summary Compensation Table, was $639,875;
- The median of the annual total compensation of all of our employees, excluding the Chief Executive Officer, was $99,308; and
- The ratio of the annual total compensation of our CEO to the median of the annual total compensation of all other employees was 6.4 to 1.

In determining the pay ratio information provided above, we first identified our median employee for 2018 by using the following methodology:

- We selected December 31, 2018 as the date upon which we would identify our median employee, and we compiled a list of all full-time, part-time and temporary employees who were employed on that date.
- We used base pay as a consistently applied compensation measure to identify our median employee from the employees on the list.

Once our median employee was identified in the manner described above, we calculated the annual total compensation of the median employee using the same methodology that we used to determine the annual total compensation of the CEO, as reported in the Summary Compensation Table.

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Post-Employment Compensation

The following table sets forth the expected benefit to be received by our Chief Executive Officer in the event of his termination resulting from various scenarios, assuming a termination date of December 31, 2018 and a stock price of $0.10, our closing stock price on December 31, 2018.

Jed A. Latkin

	For Cause	Resignation	Death	Disability	Without Cause	End of Term	Change in Control
Cash payments:							
Severance [a]	$—	$ —	$—	$—	$633,333	$—	$1,741,667
Accrued bonus [b]	—	—	—	—	271,875	—	271,875
Disability supplement [c]	—	—	—	235,100	—	—	—
Paid time off [d]	9,135	9,135	9,135	9,135	9,135	9,135	9,135
2018 401(k) match [e]	5,500	5,500	5,500	5,500	5,500	5,500	5,500
Continuation of benefits [f]	—	—	960	960	—	—	—
Stock option vesting acceleration [g]	—	—	—	—	—	—	—
Total	$14,635	$ 14,635	$15,594	$250,694	$919,843	$14,635	$2,028,176

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

(b) Amount represents accrued but unpaid bonus as of December 31, 2018.

(c) During the first 6 months of disability, the Company will supplement disability insurance payments to Mr. Latkin to achieve 100% salary replacement. As of December 31, 2018, the Company's short-term disability insurance policy pays $100 per week for a maximum of 24 weeks.

(d) Amount represents the value of 40 hours of accrued but unused vacation time as of December 31, 2018.

(e) Amount represents the value of 18,795 shares of Company stock which was accrued during 2018 as the Company's 401(k) matching contribution but was unissued as of December 31, 2018.

(f) Amount represents 21 months of dental insurance premiums at rates in effect at December 31, 2018.

(g) Pursuant to Mr. Latkin's stock option agreements, all unvested stock options outstanding will vest upon termination without cause or a change in control. Amount represents the value of the stock at $0.10, the closing price of the Company's stock on December 31, 2018, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $0.10, the closing price of the Company's stock on December 31, 2018.

Michael M. Goldberg, M.D.

Effective August 14, 2018, Dr. Michael Goldberg resigned from his positions as an executive officer and a director of Navidea. In connection with Dr. Goldberg's resignation, Navidea and Dr. Goldberg entered into the Agreement, with the intent of entering into one or more additional Definitive Agreements, which set forth the terms of his separation from service. The Agreement provides that Dr. Goldberg will be entitled to receive a severance of $978,000 payable in equal installments over two years, along with a one-time payment of approximately $35,000 which represents the cost of continuing his existing health care coverage for a period of 16 months. The Agreement also provides that Dr. Goldberg will be entitled to 23.5 million shares of common stock of Navidea, representing in part payment of accrued bonuses and payment of the balance of the Platinum Note. A portion of the 23.5 million shares to be issued to Dr. Goldberg will be held in escrow for up to 18 months in order to reimburse Navidea in the event that Navidea is obligated to pay any portion of the Platinum Note to a party other than Dr. Goldberg. Further, the Agreement provides that the Company's subsidiary, MT, will redeem all of Dr. Goldberg's preferred stock and issue to Dr. Goldberg super voting common stock equal to 5% of the outstanding shares of MT. On November 20, 2018, the Company issued 18.5 million shares of common stock of Navidea to Dr. Goldberg, 5 million of which were placed in escrow in accordance with the Agreement. As of the date of filing of this Annual Report on Form 10-K, the Definitive Agreements have not yet been signed.

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the United States District Court for the Southern District of New York, alleging breach of the Agreement, as well as a breach of the covenant of good faith and fair dealing and to obtain a declaratory judgment that Navidea's performance under the Agreement is excused and that Navidea is entitled to terminate the Agreement as a result of Dr. Goldberg's actions.

On March 7, 2019, Dr. Goldberg filed a complaint against Navidea and MT in the United States District Court for the Southern District of New York. The Complaint alleges a breach of contract claim against both Navidea and MT for failure to pay to Dr. Goldberg funds allegedly due to him under the Platinum Note. The Complaint further alleges a breach of contract claim against Navidea due to Navidea's failure to issue 23.5 million shares to Dr. Goldberg, to issue MT Super Voting Common Stock, by removing Dr. Greene from the MT Board of Directors, by appointing Mr. Rice and Dr. Bruck to the MT Board of Directors, and by terminating Dr. Goldberg as CEO of MT.

Tax Consequences

In making compensation decisions in 2017 and prior years, the CNG Committee often sought to structure certain incentive awards with the intention that they would be exempt from the $1 million deduction limit as "qualified performance-based compensation." However, the committee never adopted a policy that would have required all compensation to be deductible, because the committee wanted to preserve the ability to pay compensation to our executives in appropriate circumstances, even if such compensation would not be deductible under Section 162(m) of the Internal Revenue Code ("Section 162(m)").

The Tax Cuts and Jobs Act, which was enacted on December 22, 2017, included a number of significant changes to Section 162(m), such as the repeal of the qualified performance-based compensation exemption and the expansion of the definition of "covered employees" (for example, by including the chief financial officer and certain former named executive officers as covered employees). As a result of these changes, except as otherwise provided in the transition relief provisions of the Tax Cuts and Jobs Act, compensation paid to any of our covered employees generally will not be deductible in 2018 or future years, to the extent that it exceeds $1 million.

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 2018. 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 2018

		Estimated Future Payouts Under Non-Equity Incentive Plan Awards (a)		Estimated Future Payouts Under Equity Incentive Plan Awards		All Other Stock Awards: Number of Shares of Stock	All Other Option Awards: Number of Securities Underlying Options	Exercise Price of Option Awards	Grant Date Fair Value of Stock and Option Awards
Named Executive Officer	**Grant Date**	**Threshold**	**Maximum**	**Threshold**	**Maximum**				
Jed A. Latkin	N/A	$—	$ 271,875	—	—	—	—	$ —	$ — (b)
Michael M. Goldberg, M.D.	N/A	$—	$ 225,000	—	—	—	—	$ —	$ — (c)
Frederick O. Cope, Ph.D.	N/A	$—	$ —	—	—	—	—	$ —	$ — (d)
Michael S. Rosol, Ph.D.	N/A	$—	$ 2,949	—	—	—	—	—	$ — (e)

(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.

(b) Mr. Latkin was promoted to Chief Executive Officer effective October 1, 2018. The estimated maximum cash bonus payout to Mr. Latkin related to fiscal 2018 has been pro-rated based on the weighted average amount of his base salary during 2018.

(c) Dr. Goldberg separated from the Company during 2018. Any bonus awarded for fiscal 2018 will be paid to Dr. Goldberg in accordance with his termination agreement. Additional information regarding Dr. Goldberg's termination agreement, dated August 14, 2018, is disclosed in "Post-Employment Compensation," above.

(d) Dr. Cope separated from the Company during 2018, and as such will not receive a cash bonus related to fiscal 2018.

(e) The estimated maximum cash bonus payout to Dr. Rosol related to fiscal 2018 has been pro-rated from December 17, 2018, his effective date of employment.

Outstanding Equity Awards

The following table presents certain information concerning outstanding equity awards held by the Named Executive Officers as of December 31, 2018.

Outstanding Equity Awards Table at Fiscal 2018 Year-End

	Option Awards					**Stock Awards**				
	Number of Securities Underlying Unexercised Options (#)						**Market Value of Shares of**	**Equity Incentive Plan Awards**		
Named Executive Officer	**Exercisable**	**Unexercisable**	**Option Exercise Price**	**Option Expiration Date**	**Note**	**Number of Shares of Stock that Have Not Vested**	**Stock that Have Not Vested**	**Number of Unearned Shares**	**Market Value of Unearned Shares**	**Note**
Jed A. Latkin	45,000	—	$ 1.50	4/20/2026	(a)					
	20,000	—	$ 1.00	10/14/2026	(b)					
	—	333,334	$ 0.65	5/4/2027	(c)					
	—	333,333	$ 0.75	5/4/2027	(d)					
	—	333,333	$ 1.00	5/4/2027	(e)					
Michael M. Goldberg, M.D. (f)										
Frederick O. Cope, Ph.D. (g)										

Michael S.
Rosol, Ph.D.
(h)

(a) 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.
(b) 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.
(c) Options were granted 5/4/2017 and vest 100% when both of the following conditions have been met: May 4, 2017 and a closing market price of the Company's common stock of at least $0.85.
(d) Options were granted 5/4/2017 and vest 100% when both of the following conditions have been met: December 31, 2017 and a closing market price of the Company's common stock of at least $1.00.
(e) Options were granted 5/4/2017 and vest 100% when both of the following conditions have been met: December 31, 2018 and a closing market price of the Company's common stock of at least $1.25.
(f) Dr. Goldberg separated from the Company effective August 14, 2018. Dr. Goldberg did not hold any stock options or restricted stock on the date of separation.
(g) Dr. Cope separated from the Company effective October 30, 2018. All of Dr. Cope's unexercised stock options expired on the date of separation.
(h) Dr. Rosol commenced employment with the Company effective December 17, 2018. As of December 31, 2018, he did not hold any stock options or restricted stock.

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 2018.

Options Exercised and Stock Vested Table for Fiscal 2018

	Option Awards		Stock Awards		
Named Executive Officer	**Number of Shares Acquired on Exercise**	**Value Realized on Exercise**	**Number of Shares Acquired on Vesting**	**Value Realized on Vesting**	**Note**
Jed. A. Latkin	—	$ —	—	$ —	
Michael M. Goldberg, M.D.	—	$ —	—	$ —	
Frederick O. Cope, Ph.D.	—	$ —	—	$ —	
Michael S. Rosol, Ph.D.	—	$ —	—	$ —	

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Compensation of Non-Employee Directors

Each non-employee director received an annual cash retainer of $50,000 during the fiscal year ended December 31, 2018. The Chair of the Company's Board of Directors received an additional annual retainer of $30,000, the Chair of the Audit Committee received an additional annual retainer of $10,000, and the Chair of the CNG Committee received an additional annual retainer of $7,500 for their services in those capacities during 2018. Non-Chair members of the Audit Committee received an additional annual retainer of $2,500 and non-Chair members of the CNG Committee received an additional annual retainer of $2,500. We also reimbursed non-employee directors for travel expenses for meetings attended during 2018.

Each non-employee director also received 50,000 shares of restricted stock and 50,000 options to purchase stock at $0.75 per share during 2018 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, except for Mr. Cutler and Dr. Rouan, who received their 2018 stock incentive grants in January 2019. The restricted stock and stock options granted will vest on the first anniversary of the date of grant.

The aggregate number of equity awards outstanding at February 28, 2019 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 CNG Committee has noted that the total compensation of our Board of Directors, including cash and equity awards, is at approximately the 50th percentile for our peer group of companies, while the total compensation of our Board Committee members is less than half of the competitive market rate.

The following table sets forth certain information concerning the compensation of non-employee Directors for the fiscal year ended December 31, 2018.

Name	(a) Fees Earned or Paid in Cash	(b),(c) Option Awards	(d),(e) Stock Awards	All Other Compensation	Total Compensation
Claudine Bruck, Ph.D. (f)	$47,111	$ 9,659	$19,150	$ —	$ 75,920
Adam D. Cutler (g)	4,212	—	—	—	4,212
Mark I. Greene, M.D., Ph.D. (h)	36,486	9,226	17,955	—	63,667

Y. Michael Rice	73,750	9,226	17,955	—	100,931
S. Kathryn Rouan, Ph.D. (g)	4,212	—	—	—	4,212
Eric K. Rowinsky, M.D. (i)	45,000	9,226	17,955	—	72,181

(a) Amount represents fees earned during the fiscal year ended December 31, 2018 (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) During the year ended December 31, 2018, the non-employee directors were issued an aggregate of 200,000 options to purchase common stock which vest as to 100% of the shares on the first anniversary of the date of grant. At December 31, 2018, the non-employee directors held an aggregate of 150,000 options to purchase common stock. Mr. Rice held 100,000 options, and Dr. Bruck held 50,000 options to purchase shares of common stock.

(d) Amount represents the aggregate grant date fair value in accordance with FASB ASC Topic 718.

(e) During the year ended December 31, 2018, the non-employee directors were issued an aggregate of 200,000 shares of restricted stock which vest as to 100% of the shares on the first anniversary of the date of grant. At December 31, 2018, the non-employee directors held an aggregate of 100,000 shares of unvested restricted stock. Mr. Rice and Dr. Bruck each held 50,000 shares of unvested restricted stock.

(f) Dr. Bruck was appointed to the Board of Directors effective March 15, 2018.

(g) Mr. Cutler and Dr. Rouan were appointed to the Board of Directors effective December 1, 2018, but did not receive their 2018 stock incentive grants until January 2019.

(h) Dr. Greene resigned from the Board of Directors effective August 14, 2018. His unvested stock options and restricted stock were forfeited upon his resignation.

(i) Dr. Rowinsky retired from the Board of Directors effective March 31, 2018. All of his unvested stock options and restricted stock vested upon his retirement, and his stock options are exercisable until June 30, 2019. The Company also paid Dr. Rowinsky Board and committee fees through June 30, 2018 in an aggregate amount of $45,000.

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, 2018, 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.

Plan Category	**(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]	3,158,169	$ 1.24	10,293,824
Equity compensation plans not approved by security holders	—	—	—
Total	3,158,169	$ 1.24	10,293,824

(a) Our stockholders ratified the 2014 Stock Incentive Plan (the "2014 Plan") at the 2014 Annual Meeting of Stockholders held on July 17, 2014, and amended the 2014 Plan at the 2018 Annual Meeting of Stockholders held

on August 16, 2018. The total number of shares available for awards under the 2014 Plan shall not exceed 15,000,000 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 2,454,555 issued under the 2014 Plan and 703,614 issued under the 2002 Plan.

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

The following table sets forth, as of February 28, 2019, 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 (**)**	
Claudine Bruck, Ph.D.	100,000	(a)	—	(m)
Frederick O. Cope, Ph.D.	594,649	(b)	—	(m)
Adam D. Cutler	—	(c)	—	(m)
Michael M. Goldberg, M.D.	24,421,023	(d)	12.2	%
Jed A. Latkin	127,230	(e)	—	(m)
Y. Michael Rice	200,000	(f)	—	(m)
Michael S. Rosol, Ph.D.	41,667	(g)	—	(m)
S. Kathryn Rouan, Ph.D.	—	(h)	—	(m)
All directors and executive officers as a group (6 persons)	468,897	(i)(n)	—	%(m)
Cardinal Health, Inc.	10,000,000	(j)	5.0	%
John K. Scott, Jr.	22,107,207	(k)	11.0	%
Platinum-Montaur Life Sciences, LLC	18,329,799	(l)	9.1	%

(*) 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, 2019, plus the number of shares the person has the right to acquire within 60 days of February 28, 2019.

(a) This amount includes 50,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 50,000 shares of unvested restricted stock and 50,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(b) Dr. Cope separated from the Company effective October 30, 2018. This amount is based on Dr. Cope's most recent SEC ownership filings as well as the Company's best knowledge and belief. This amount includes 32,373 shares in Dr. Cope's account in the 401(k) Plan. All of Dr. Cope's unexercised stock options expired upon his separation from employment.

(c) This amount does not include 100,000 shares of unvested restricted stock and 100,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(d)

Dr. Goldberg separated from the Company effective August 14, 2018. This amount is based on Dr. Goldberg's most recent SEC ownership filings as well as the Company's best knowledge and belief.

(e) This amount includes 65,000 shares issuable upon exercise of options which are exercisable within 60 days and 12,071 shares in Mr. Latkin's account in the 401(k) Plan, but does not include 2,000,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(f) The amount includes 100,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 50,000 shares of unvested restricted stock and 50,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(g) This amount includes 41,667 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 83,333 shares issuable upon exercise of options which are not exercisable within 60 days.

(h) This amount does not include 100,000 shares of unvested restricted stock and 100,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(h) This amount does not include 100,000 shares of unvested restricted stock and 100,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(i) This amount includes 256,667 shares issuable upon exercise of options which are exercisable within 60 days, and 44,444 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 300,000 shares of unvested restricted stock and 2,100,000 shares issuable upon the exercise of options which are not exercisable within 60 days. The Company's Chief Executive Officer, Chief Operating Officer and Chief Financial Officer, Jed A. Latkin, 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. Mr. Latkin disclaims any beneficial ownership of shares held by the 401(k) Plan. The 401(k) Plan holds an aggregate total of 182,017 shares of common stock.

(j) The number of shares beneficially owned is based on a Schedule 13G filed by Cardinal Health, Inc. with the SEC on March 13, 2017. This amount includes 10,000,000 shares of common stock issuable upon exercise of Series NN warrants at an exercise price of $1.50 per share. The address of Cardinal Health, Inc. is 7000 Cardinal Place, Dublin, OH 43017.

(k) The number of shares beneficially owned is based on a Schedule 13G filed by John K. Scott, Jr. with the SEC on September 24, 2018. The address of John K. Scott, Jr. is 5251 DTC Parkway, Suite 285, Greenwood Village, CO 80111.

(l) The number of shares beneficially owned is based on a Schedule 13D/A filed by Platinum and certain of its affiliates with the SEC on June 28, 2016. This amount includes (i) 13,964,519 shares of our common stock, and (ii) 4,365,280 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). The address of Platinum is c/o Otterbourg P.C., 230 Park Avenue, New York, NY 10169.

(m) Less than one percent.

(n) The address of all directors and executive officers is c/o Navidea Biopharmaceuticals, Inc., 4995 Bradenton Avenue, Suite 240, 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 former President and Chief Executive Officer, previously managed a portfolio of funds for Platinum-Montaur Life Sciences LLC (“Platinum-Montaur”), an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P. (“PPVA”), Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, “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 Platinum Partners Capital Opportunity Fund L.P. ("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 were transferred by Platinum-Montaur to PPCO.

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages of approximately $1.9 million purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted were for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement. The action was removed to the United States District Court for the Southern District of New York (the "District Court") on December 6, 2017. An initial pretrial conference was held on January 26, 2018 and a follow up status conference was held on March 9, 2018, during which the District Court set a briefing schedule and determined that Navidea's motion to dismiss was due on April 6, 2018. The Company filed its motion to dismiss in advance of the filing deadline. On October 31, 2018, the District Court granted judgment for Navidea and dismissed all claims in the case. The District Court stated that Platinum-Montaur had no standing to assert any contractual interest in funds that might be due under the Platinum Loan Agreement. The District Court also disagreed with Platinum-Montaur's claim of unjust enrichment on similar grounds and found that Platinum-Montaur lacked any sufficient personal stake to maintain claims against Navidea. The claims against Navidea were dismissed without prejudice on the grounds of lack of standing to pursue the claims asserted.

On November 30, 2018, Platinum-Montaur filed a notice of appeal with the United States Court of Appeals for the Second Circuit (the "Second Circuit") claiming that the District Court erred in dismissing Platinum-Montaur's claims for breach of contract and unjust enrichment. On January 22, 2019, Platinum-Montaur filed its brief in the Second Circuit, asking the Second Circuit to reverse the District Court and remand the case to the District Court for further proceedings. On February 26, 2019, the Company filed its brief in the Second Circuit. It is not known at this time whether the Second Circuit will hold oral argument on this matter or when the Second Circuit will render its decision.

Effective August 14, 2018, Dr. Michael Goldberg resigned from his positions as an executive officer and a director of Navidea. In connection with Dr. Goldberg's resignation, Navidea and Dr. Goldberg entered into the Agreement, with the intent of entering into one or more additional Definitive Agreements, which set forth the terms of his separation from service. The Agreement provides that Dr. Goldberg will be entitled to receive a severance of $978,000 payable in equal installments over two years, along with a one-time payment of approximately $35,000 which represents the cost of continuing his existing health care coverage for a period of 16 months. The Agreement also provides that Dr. Goldberg will be entitled to 23.5 million shares of common stock of Navidea, representing in part payment of accrued bonuses and payment of the balance of the Platinum Note. A portion of the 23.5 million shares to be issued to Dr. Goldberg will be held in escrow for up to 18 months in order to reimburse Navidea in the event that Navidea is obligated to pay any portion of the Platinum Note to a party other than Dr. Goldberg. Further, the Agreement provides that the Company's subsidiary, MT, will redeem all of Dr. Goldberg's preferred stock and issue to Dr. Goldberg super voting common stock equal to 5% of the outstanding shares of MT. On November 20, 2018, the Company issued 18.5 million shares of common stock of Navidea to Dr. Goldberg, 5 million of which were placed in escrow in accordance with the Agreement. As of the date of filing of this Annual Report on Form 10-K, the Definitive Agreements have not yet been signed.

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the United States District Court for the Southern District of New York, alleging breach of the Agreement, as well as a breach of the covenant of good faith and fair dealing and to obtain a declaratory judgment that Navidea's performance under the Agreement is excused and that Navidea is entitled to terminate the Agreement as a result of Dr. Goldberg's actions.

On March 7, 2019, Dr. Goldberg filed a complaint against Navidea and MT in the United States District Court for the Southern District of New York. The Complaint alleges a breach of contract claim against both Navidea and MT for failure to pay to Dr. Goldberg funds allegedly due to him under the Platinum Note. The Complaint further alleges a breach of contract claim against Navidea due to Navidea's failure to issue 23.5 million shares to Dr. Goldberg, to issue MT Super Voting Common Stock, by removing Dr. Greene from the MT Board of Directors, by appointing Mr. Rice and Dr. Bruck to the MT Board of Directors, and by terminating Dr. Goldberg as CEO of MT.

Jed A. Latkin, our Chief Executive Officer, 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 PPCO. 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 former 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 was subsequently 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. Dr. Rowinsky retired from the Company's Board of Directors effective March 31, 2018.

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 consisted 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 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. 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 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.

During 2018, the largest aggregate amount of principal outstanding under the Platinum credit facility was $2.2 million, and as of December 31, 2018, the amount of principal outstanding was $0.

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 Exchange Act and Section 803A of the NYSE American Company Guide. Our Board of Directors has determined that Drs. Bruck and Rouan, and Messrs. Cutler and Rice, meet the independence requirements. The Board had also concluded that Drs. Greene and Rowinsky were independent during the time each served as a director until their departure in 2018.

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 2018 fiscal year and the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2018 fiscal year were $275,850 (including direct engagement expenses).

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 2017 fiscal year, the audit of the Company's internal control over financial reporting as of December 31, 2017, and the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2017 fiscal year were $342,160 (including direct engagement expenses).

Audit-Related Fees. No fees were billed by Marcum LLP for audit-related services for the 2018 or 2017 fiscal years.

Tax Fees. No fees were billed by Marcum LLP for tax-related services for the 2018 or 2017 fiscal years.

All Other Fees. No fees were billed by Marcum LLP for services other than the audit, audit-related and tax services for the 2018 or 2017 fiscal years.

Pre-Approval Policy. The Audit Committee is required to pre-approve all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for the Company by its independent auditor or other registered public accounting firm, subject to the *de minimis* exceptions for permitted non-audit services described in Section 10A(i)(1)(B) of the Exchange Act 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:

(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) (filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K filed March 31, 2017, and incorporated therein by reference).
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	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 U.S. 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).
10.4	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).
10.5	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).
10.6	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/A filed June 28, 2013).

10.7	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/A filed June 28, 2013).
10.8	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/A filed June 28, 2013).
10.9	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/A filed June 28, 2013).
10.10	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 U.S. 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).
10.11	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 U.S. 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).

Exhibit Number	Exhibit Description
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16	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 U.S. 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).
10.17	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 U.S. 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).
10.18	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). ^
10.19	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). ^
10.20	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). ^
10.21	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).
10.22	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).^

10.23	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).
10.24	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 U.S. 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).
10.25	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).
10.26	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).

Exhibit Number	Exhibit Description
10.27	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).
10.28	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).
10.29	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).
10.30	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).
10.31	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).
10.32	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).
10.33	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).
10.34	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).
10.35	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).
10.36	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). ^

10.37	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 99.1 to the Company's Current Report on Form 8-K filed June 29, 2016).
10.38	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). ^
10.39	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).
10.40	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 9, 2017).
10.41	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 9, 2017).

Exhibit Number	Exhibit Description
10.42	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 9, 2017).
10.43	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 9, 2017).
10.44	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 9, 2017).
10.45	Employment Agreement, dated May 4, 2017, between Navidea Biopharmaceuticals, Inc. and Jed A. Latkin (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed May 10, 2017).^
10.46	Amendment to Asset Purchase Agreement dated April 2, 2018, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed May 9, 2018).
10.47	Agreement dated August 14, 2018, by and among Navidea Biopharmaceuticals, Inc., Macrophage Therapeutics, Inc. and Michael M. Goldberg, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed November 9, 2018).
10.48	Stock Purchase Agreement dated September 13, 2018, by and between Navidea Biopharmaceuticals, Inc. and John K. Scott, Jr. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 9, 2018).
10.49	Employment Agreement, effective October 1, 2018, by and 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 filed October 5, 2018).^
10.50	Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan (as amended and restated on August 16, 2018) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 21, 2018).
21.1	Subsidiaries of the registrant.*
23.1	Consent of Marcum LLP.*
24.1	Power of Attorney.*
31.1	

	Certification of Chief Executive Officer, Chief Operating Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
32.1	Certification of Chief Executive Officer, Chief Operating Officer and 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.
**Furnished 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 15, 2019

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)

By: */s/ Jed A. Latkin*
Jed A. Latkin
Chief Executive Officer, Chief Operating Officer and

Chief Financial Officer

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

Signature	**Title**	**Date**
*/s/ Jed A. Latkin** Jed A. Latkin	Chief Executive Officer, Chief Operating Officer and Chief Financial Officer, Director (principal executive officer, principal financial officer and principal accounting officer)	March 15, 2019
*/s/ Y. Michael Rice** Y. Michael Rice	Chairman, Director	March 15, 2019
*/s/ Claudine Bruck** Claudine Bruck, Ph.D.	Director	March 15, 2019
*/s/ Adam D. Cutler** Adam D. Cutler	Director	March 15, 2019
*/s/ S. Kathryn Rouan**	Director	

March 15, 2019

S. Kathryn Rouan, Ph.D.

By:/s/ Jed A. Latkin*
Jed A. Latkin, Attorney-in-fact

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

NAVIDEA BIOPHARMACEUTICALS, INC.

FORM 10-K ANNUAL REPORT

As of December 31, 2018 and 2017

and for Each of the

Two Years in the Period Ended

December 31, 2018

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

To the Shareholders and Board of Directors of

Navidea Biopharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Navidea Biopharmaceuticals, Inc. (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive (loss) income, stockholders’ (deficit) equity and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum llp

We have served as the Company’s auditor since 2016.

New Haven, CT

March 15, 2019

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$3,475,881	$2,795,006
Available-for-sale securities	799,270	1,797,604
Accounts and other receivables	21,151	8,137,872
Prepaid expenses and other	1,299,454	1,101,923
Total current assets	5,595,756	13,832,405
Property and equipment	1,251,185	1,206,058
Less accumulated depreciation and amortization	1,089,013	969,357
Property and equipment, net	162,172	236,701
License agreements, patents and trademarks	480,404	480,404
Less accumulated amortization	51,912	22,248
License agreements, patents and trademarks, net	428,492	458,156
Guaranteed earnout receivable	—	4,809,376
Other assets	835,107	1,444,798
Total assets	$7,021,527	$20,781,436
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$424,718	$855,043
Accrued liabilities and other	2,517,047	1,857,848
Notes payable	316,074	2,353,639
Terminated lease liability, current	120,679	107,215
Accrued loss for CRG litigation	—	2,887,566
Liabilities associated with discontinued operations, current	—	7,092
Total current liabilities	3,378,518	8,068,403
Terminated lease liability	468,494	588,092
Deferred revenue	700,000	11,024
Other liabilities	64,055	65,587
Total liabilities	4,611,067	8,733,106
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at December 31, 2018 and 2017	—	—
Common stock; $.001 par value; 300,000,000 shares authorized; 200,390,700 and 162,206,646 shares issued and outstanding at December 31, 2018 and 2017, respectively	200,391	162,207
Additional paid-in capital	338,265,383	331,128,787
Accumulated deficit	(336,722,905)	(319,908,968)

Accumulated other comprehensive loss	(730)	(2,396)
Total Navidea stockholders' equity	1,742,139	11,379,630
Noncontrolling interest	668,321	668,700
Total stockholders’ equity	2,410,460	12,048,330
Total liabilities and stockholders’ equity	$7,021,527	$20,781,436

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

	Years Ended December 31,	
	2018	**2017**
Revenue:		
Royalty revenue	$15,347	$9,126
License revenue	307,174	100,000
Grant and other revenue	846,830	1,701,311
Total revenue	1,169,351	1,810,437
Cost of revenue	96,636	3,651
Gross profit	1,072,715	1,806,786
Operating expenses:		
Research and development	4,221,881	4,513,842
Selling, general and administrative	7,698,135	11,169,951
Total operating expenses	11,920,016	15,683,793
Loss from operations	(10,847,301)	(13,877,007)
Other expense:		
Interest (expense) income, net	(30,799)	168,971
Change in fair value of financial instruments	—	153,357
Loss on extinguishment of debt	(5,291,616)	(4,201,668)
Other income (expense), net	1,145	(33,339)
Total other expense, net	(5,321,270)	(3,912,679)
Loss before income taxes	(16,168,571)	(17,789,686)
Benefit from income taxes	9,753	4,062,489
Loss from continuing operations	(16,158,818)	(13,727,197)
Discontinued operations, net of tax effect:		
Income (loss) from discontinued operations	1,449	(490,758)
Gain on sale	43,053	89,163,811
Net (loss) income	(16,114,316)	74,945,856
Less loss attributable to noncontrolling interest	(379)	(210)
Net (loss) income attributable to common stockholders	$(16,113,937)	$74,946,066
(Loss) income per common share (basic):		
Continuing operations	$(0.09)	$(0.08)
Discontinued operations	$—	$0.55
Attributable to common stockholders	$(0.09)	$0.47
Weighted average shares outstanding (basic)	170,535,343	161,592,569
(Loss) income per common share (diluted):		
Continuing operations	$(0.09)	$(0.08)
Discontinued operations	$—	$0.53
Attributable to common stockholders	$(0.09)	$0.45
Weighted average shares outstanding (diluted)	170,535,343	166,016,458

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Comprehensive (Loss) Income

	Years Ended December 31,	
	2018	**2017**
Net (loss) income	$(16,114,316)	$74,945,856
Unrealized gain (loss) on available-for-sale securities	1,666	(2,396)
Comprehensive (loss) income	$(16,112,650)	$74,943,460

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Stockholders' (Deficit) Equity

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Compre-hensive	Non-controlling	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Loss	Interest	Equity
Balance, January 1, 2017	155,762,729	$155,763	$326,564,148	$(394,855,034)	$ —	$468,910	$(67,666,213)
Issued stock in payment of Board retainers	16,406	17	10,483	—	—	—	10,500
Issued stock in payment of employee bonuses	710,353	710	368,632	—	—	—	369,342
Issued stock upon exercise of warrants	5,411,850	5,412	48,707	—	—	—	54,119
Issued warrants in connection with Asset Sale			3,337,187	—	—	—	3,337,187
Issued warrants for extension of license agreement			333,719	—	—	—	333,719
Issued stock to 401(k) plan	105,308	105	53,602	—	—	—	53,707
Issued restricted stock	200,000	200		—	—	—	200
Canceled forfeited restricted stock	(50,000)	(50)	50	—	—	—	—
Issued stock upon exercise of stock options	50,000	50	18,050	—	—	—	18,100
Stock compensation expense	—	—	394,209	—	—	—	