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, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THESECURITIES EXCHANGE ACT OF 1934**

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:

Title of Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, par value $.001 per share	NAVB	NYSE American

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 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, 2019 was $11,351,428.

The number of shares of common stock outstanding on March 2, 2020 was 20,439,541.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

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, the impact of the recent coronavirus pandemic, 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, the Company completed the 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, including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration (the "FDA") and similar indications approved by the FDA in the future (the "Acquired Assets"), in Canada, Mexico and the United States (the "Asset Sale"). 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 a settlement reached in litigation with Capital Royalty Partners II L.P. ("CRG"), (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 additions to the purchase price) to the Company based on net sales derived from the purchased Product.

On April 2, 2018, the Company entered into an Amendment to the Purchase Agreement (the "Amendment"). 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 in favor of CRG (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. On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit.

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 (sublicensed in April 2018), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform. See Note 17 to the accompanying consolidated financial statements for more information about our business segments.

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. Beginning in late 2011, the Company in-licensed two neuro-tracer product candidates, NAV4694 and NAV5001. The Company advanced 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 sublicense 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 developed processes for producing the first two therapeutic Manocept immuno-constructs, MT-1002, which is designed to specifically target and kill activated CD206+ macrophages by delivering doxorubicin, and MT-2002, which is designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent. We have 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.

Goldberg Litigation

In August 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 an Agreement (the "Goldberg Agreement"), with the intent of entering into one or more additional Definitive Agreements, which set forth the terms of the separation from service. Among other things, the Goldberg Agreement provided that Dr. Goldberg would be entitled to 1,175,000 shares of our Common Stock, representing in part payment of accrued bonuses and payment of the balance of the Platinum debt. A portion of the 1,175,000 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 debt to a party other than Dr. Goldberg. Further, the Goldberg Agreement provided that the Company's subsidiary, MT, would 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. In November 2018, the Company issued 925,000 shares of our Common Stock to Dr. Goldberg, 250,000 of which were placed in escrow in accordance with the Goldberg Agreement.

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 in accordance with its terms, effective March 1, 2019, due to MT's insolvency. On February 20, 2019, the MT Board 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 Jed A. Latkin to serve as President and Chief Executive Officer of MT.

New York Litigation Involving Dr. Goldberg

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the United States District Court, Southern District of New York (the "District Court"), alleging breach of the Goldberg 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 Goldberg Agreement is excused and that Navidea is entitled to terminate the Goldberg Agreement as a result of Dr. Goldberg's actions. On April 26, 2019, Navidea filed an amended complaint against Dr. Goldberg which added a claim for breach of fiduciary duty seeking damages related to certain actions Dr. Goldberg took while CEO of Navidea. On June 13, 2019, Dr. Goldberg answered the amended complaint and asserted counterclaims against Navidea and third-party claims against MT for breach of the Goldberg Agreement, wrongful termination, injunctive relief, and quantum meruit.

On December 26, 2019, the District Court ruled on several motions related to Navidea and MT and Dr. Goldberg that substantially limited the claims that Dr. Goldberg can pursue against Navidea and MT. Specifically, the District Court found that certain portions of Dr. Goldberg's counterclaims against Navidea and third-party claims against Macrophage failed to state a claim upon which relief can be granted. Specifically, the District Court ruled that actions taken by Navidea and MT, including reconstituting the MT Board, replacing Dr. Goldberg with Mr. Latkin as Chief Executive Officer of MT, terminating the sublicense between Navidea and MT, terminating certain research projects, and allowing MT intellectual property to revert back to Navidea, were not breaches of the Goldberg Agreement.

The District Court also rejected Dr. Goldberg's claim for wrongful termination as Chief Executive Officer of MT. In addition, the District Court found that Dr. Goldberg lacked standing to seek injunctive relief to force the removal of Dr. Claudine Bruck and Michael Rice from MT's Board of Directors, to invalidate all actions taken by the MT Board on or after November 29, 2018 (the date upon which Dr. Bruck and Mr. Rice were appointed by Navidea to the Board of MT), or to reinstate the terminated sublicense between Navidea and MT.

In addition, the District Court found Navidea's breach of fiduciary duty claim against Dr. Goldberg for conduct occurring more than three years prior to the filing of the complaint to be time-barred and that Dr. Goldberg is entitled to an advancement of attorneys' fees solely with respect to that claim. The parties are in the process of submitting the issue to the District Court for resolution on how much in fees Dr. Goldberg is owed under the District Court's order. On January 27, 2020, Dr. Goldberg filed a motion seeking additional advancement from Navidea for fees in connection with the New York Action and the Delaware Action. Navidea has opposed the motion.

On January 31, 2020, Goldberg filed a motion for leave to amend his complaint to add back in claims for breach of contract, breach of the implied covenant of good faith and fair dealing, quantum meruit and injunctive relief. Navidea and MT have opposed the motion. The discovery deadline in the New York Action is April 15, 2020.

Delaware Litigation Involving Dr. Goldberg

On February 20, 2019, MT initiated a suit against Dr. Goldberg in the Court of Chancery of the State of Delaware (the "Delaware Court"), 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 effect are void. On June 12, 2019, the Delaware Court found that Dr. Goldberg's actions were not authorized in compliance with the Delaware General Corporate Law. Specifically, the Delaware Court found that Dr. Goldberg's creation of a new subsidiary of MT and the purported assignment by Dr. Goldberg of MT's intellectual property to that subsidiary were void. The Delaware Court's ruling follows the order on May 23, 2019 in the case, in which it found Dr. Goldberg in contempt of its prior order holding Dr. Goldberg responsible for the payment of MT's fees and costs to cure the damages caused by Dr. Goldberg's contempt. MT's claims for breach of fiduciary duty and conversion against Dr. Goldberg remain pending. As a result of the Delaware Court's ruling and Navidea's prior termination of the sublicense between itself and MT, all of the intellectual property related to the Manocept platform is now directly controlled by Navidea. A trial on MT's claims against Goldberg for breach of fiduciary duty and conversion is presently scheduled for June 2020.

Derivative Action Involving Dr. Goldberg

On July 26, 2019, Dr. Goldberg served shareholder demands on the Boards of Navidea and MT repeating many of the claims made in the lawsuits described above. On or about November 20, 2019, Dr. Goldberg commenced a derivative action purportedly on behalf of MT in the District Court against Dr. Claudine Bruck, Y. Michael Rice, and Jed Latkin alleging a claim for breach of fiduciary duty based on the actions alleged in the demands. On January 30, 2020, a pre-motion conference was conducted before the District Court on an anticipated motion to dismiss and Dr. Goldberg has agreed to dismiss the derivative action in New York without prejudice and retains the ability to re-file the action in Delaware. See Note 14 to the accompanying consolidated financial statements.

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 backbone 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"), leishmaniasis, 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.

The Company has developed processes for producing the first two therapeutic Manocept immuno-construct series, MT-1000 series, which is designed to specifically target and kill or modify activated CD206+ macrophages by delivering doxorubicin, and MT-2000 series, which is designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent, dexamethasone. We have contracted with independent facilities to improve chemical syntheses and to produce sufficient quantities of the MT-1000 series and MT-2000 series agents along with the concomitant analytical standards, to provide material for planned preclinical animal studies and future clinical trials.

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, 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 of this Phase 1/2 study were presented at the June 2018 and June 2019 SNMMI meetings, the 2018 European League Against Rheumatism meeting and the 2018 ACR meeting. These studies have been combined and submitted for peer review publication and full published results will follow.

In June 2019, the results of the Company's NAV3-21 clinical study were presented at the SNMMI Annual Meeting in Anaheim, California. The presentation, titled "A Phase 1/2 Study of Intravenously Administered Tc99m Tilmanocept to Determine Safety, Tolerability, Optimal Clinical Dose Selection, and Imaging Timepoint in Patients Clinically Diagnosed with Rheumatoid Arthritis," was delivered by Arash Kardan, M.D. In addition, an abstract of the presentation was published in the *Journal of Nuclear Medicine* (2019, Volume 60, Supplement 1). The NAV3-21 study enrolled subjects with active, moderate-to-severe RA, and healthy controls. Results from the completed trial demonstrate that Tc99m tilmanocept is well-tolerated with no serious adverse events, adverse drug reactions, or drug-related adverse events observed. Additionally, static planar images revealed joint-specific Tc99m tilmanocept localization in RA subjects to disease-involved joints of the shoulders, knees, hands, and feet, but no joint-specific localization in healthy control subjects, revealing potentially significant immunodiagnostic information about CD206-expressing synovial macrophage involvement in RA. An optimal imaging time window post-Tc99m tilmanocept IV administration, as well as optimal dosing, were also determined.

In April 2019, the Company received feedback from the FDA regarding the Company's planned clinical studies that will evaluate joint disease in patients with RA and monitor patient response to therapy. The Company's proposed RA studies were discussed with the FDA during an in-person meeting and through follow-up collaborative efforts. The FDA has communicated that the first study, a Phase 2b trial, is aligned with expectations for the studies and that they will continue to work with Navidea as we progress into a second Phase 2b trial correlating Tc99m tilmanocept uptake in RA-involved joints with CD206 immunohistochemistry findings from synovial biopsies and into the planned Phase 3 clinical trial. In May 2019, we began enrolling patients into the first Phase 2b study, entitled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value ("TUV") on Tc99m Tilmanocept Planar Imaging" (ClinicalTrials.gov MCT03938636). This study will provide confirmatory support necessary to initiate Navidea's Phase 3 study program. In October 2019, the Company performed its first interim analysis of this trial, covering subjects enrolling into Arms 1 and 2. The results of this interim analysis were in line with the Company's hypotheses that Tc99m tilmanocept can provide robust, stable imaging in healthy subjects as well as in patients with active RA, and provide the fundamental information needed to keep moving forward into the Phase 3. The pivotal Phase 3 study program will assess joint disease status and monitor patient response to therapy.

Cardiovascular Disease ("CV")

In collaboration with researchers at Massachusetts General Hospital, Navidea has completed one and has 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 and SC-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.

Navidea has also been awarded a $225,000 phase 1 Small Business Technology Transfer grant (1R41HL147640-01A1) entitled *Gallium 68 Tilmanocept for PET Imaging of Atherosclerosis Plaques*. This grant will support a research collaboration between Navidea and Dr. Suzanne Lapi of the University of Alabama Birmingham. These efforts will evaluate [68]gallium tilmanocept for imaging plaques in an animal model of atherosclerosis and began activities in the fourth quarter of 2019.

Kaposi's Sarcoma

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 and initiated a Phase 1/2 clinical study in KS in 2017. This trial has completed enrollment and imaging. Data and image analysis for this study are ongoing.

Colorectal Cancer ("CRC") and Synchronous Liver Metastases

During 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. The final study report has been completed and submitted to the FDA.

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.

Tuberculosis ("TB")

In April 2019, we announced that Professor Mike Sathekge, MBChB, M. Med (Nuclear Medicine), PhD, Professor and Head of the Department of Nuclear Medicine in the Faculty of Health Sciences at the University of Pretoria/Steve Biko Academic Hospital, planned to initiate a comparative study evaluating the use of tilmanocept in patients with TB. The purpose of the study is to explore using 68Ga tilmanocept as an aid in TB patient management while contributing to the better understanding of the biology of TB granulomas. The TB granuloma plays multiple roles in tuberculous infection, although much remains unknown about its biology. Macrophages constitute one of the most abundant cell types in the TB granuloma. A molecular probe such as 68Ga-labeled tilmanocept targeting mannose receptor CD206 expressed on macrophages, therefore, holds great promise not only in understanding the behavior of TB granulomas, but may serve as a vehicle for delivering therapeutic interventions in the future. Comparing findings on 68Ga tilmanocept PET/CT and FDG PET/CT will contribute to the understanding of the biology of TB granuloma. Navidea has provided tilmanocept for use in this study, and several subjects have been injected and imaged to date. Successful completion of this study could lead to an extended claim of 68Ga-tilmanocept.

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 ongoing.

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

The therapeutic drug delivery 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 series is designed to deplete activated macrophages via apoptosis and/or alter the phenotype of macrophages. The MT-2000 series 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).

Other Immunotherapeutic Applications

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

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.

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 2020 in the United States alone. Additionally, the ACS estimates that approximately 1.8 million new cancer cases will be diagnosed in the United States during 2020. 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.

NAV4694 - Alzheimer's Disease Market Overview

The Alzheimer's Association ("AA") estimates that more than 5.8 million Americans had AD in 2019. 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 2017, deaths from AD have risen 145% while deaths attributed to the number one cause of death, heart disease, decreased 9% during the same period. AA estimates that total costs for AD care was approximately $290 billion in 2019. AA also estimates that there are over 16 million AD and dementia caregivers providing 18.5 billion hours of unpaid care valued at $234 billion.

Marketing and Distribution

As discussed previously under "Development of the Business," in March 2017 Navidea completed the sale to Cardinal Health 414 of all of its assets used in operating its business of developing, manufacturing and commercializing the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark in Canada, Mexico and the United States. Upon closing of the sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated and Cardinal Health 414 assumed responsibility for marketing Lymphoseek in those territories.

Unlike in 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. 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.

In August 2014, Navidea entered into an exclusive agreement with Beijing Sinotau Medical Research Co., Ltd. ("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 maintain 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. We may not be successful in completing 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, inflammatory, and neurology diagnostic imaging agents and other diagnostic modalities. 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

Some 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 the University of California, San Diego ("UCSD") to Navidea for the exclusive world-wide rights in all diagnostic and therapeutic uses of tilmanocept, except for the use of Tc99m tilmanocept in lymphatic mapping in Canada, Mexico and the United States, which rights have been licensed directly to Cardinal Health 414 by UCSD. 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 including issued patents and patent applications in the United States and certain major foreign markets.

The first composition of matter patent covering tilmanocept was issued to UCSD 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 by Navidea 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 2040.

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."

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.

You may also review our electronically filed reports and other information that we file with the SEC on 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-32 of this Form 10-K.

Employees

As of March 2, 2020, we had 13 full-time and 4 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, par value $0.001 per share ("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.

As discussed previously under "Development of the Business," in March 2017 Navidea completed the sale to Cardinal Health 414 of all of its assets used in operating its business of developing, manufacturing and commercializing the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark in Canada, Mexico and the United States. Upon closing of the sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated and Cardinal Health 414 assumed responsibility for marketing Lymphoseek in those territories. Under the terms of the sale, 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, which may be delayed due to the coronavirus outbreak 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 in the EU. 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.

A pandemic, epidemic or outbreak of an infectious disease in the United States may adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our development and commercialization efforts may be adversely affected. In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. In January 2020, the World Health Organization declared this outbreak a "Public Health Emergency of International Concern," and the U.S. Department of Health and Human Services declared a public health emergency to aid the U.S. healthcare community in responding to COVID-19. This virus continues to spread globally and, as of March 2020, has spread to over 100 countries, including the United States. The spread of COVID-19 has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities and our supply chain. For example, the COVID-19 outbreak may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results, and could delay our ability to obtain regulatory approval and commercialize our product candidates. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver clinical drug supplies on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations. The extent to which the recent global coronavirus pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain or treat its impact, among others. Any significant infectious disease outbreak, including the COVID-19 pandemic, could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations, including our ability to obtain additional funding, if needed. The Company is currently working to enhance its business continuity plans to include measures to protect our employees in the event of infection in our corporate offices, or in response to potential mandatory quarantines.

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. Any interruption in manufacturing across the supply chain, whether by natural disasters, global disease outbreaks such as COVID-19 (coronavirus) or otherwise, could significantly and adversely affect our operations, and delay our research and development programs.

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;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak, which may require us to change the ways in which our clinical trials are conducted, and which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays or difficulties in enrolling patients in our clinical trials, including as a result of impacts associated with the COVID-19 pandemic; 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 current 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 payors, 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 payor of patients' healthcare costs. Third-party payors 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 payors 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 nine years. Expiration of the patents underlying our technology, in the absence of extensions or other trade secret or intellectual property protection, may have a material and adverse effect on us.

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

We typically require our employees, consultants, advisers and suppliers to execute confidentiality and assignment of invention agreements in connection with their employment, consulting, advisory, or supply relationships with us. They may breach these agreements and we may not obtain an adequate remedy for breach. Further, third parties may gain unauthorized access to our trade secrets or independently develop or acquire the same or equivalent information.

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

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

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

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

With respect to Manocept and NAV4694, we have licensed certain issued patents and pending patent applications covering the respective technologies underlying these product candidates and their commercialization and use and we have licensed certain issued patents and pending patent applications directed to product compositions and chemical modifications used in product candidates for commercialization, and the use and the manufacturing thereof.

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

We may become involved in disputes with licensors or potential future collaborators over intellectual property ownership, and publications by our research collaborators and scientific advisors could impair our ability to obtain patent protection or protect our proprietary information, which, in either case, could have a significant effect on our business.

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

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 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.

Our ability to raise additional capital may also be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 NYSE American. 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) $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, (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) $6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. As of December 31, 2019 and 2018, Navidea had stockholders' (deficit) equity of approximately $(1.6 million) and $1.7 million, respectively. In addition, the Company had stockholders' deficits for several years prior to December 31, 2018, 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 February 29, 2020, the Company's total value of market capitalization was approximately $20.0 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 will delist the Company's Common Stock.

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. Navidea was advised by the NYSE American that if we failed to regain compliance with the NYSE American continued listing standards by February 14, 2020, the NYSE American would commence delisting procedures.

On February 14, 2020, the Company announced that the Company had regained compliance with NYSE American continued listing standards. However, there can be no assurance that the Company will be able to continue to meet the NYSE American's continued listing standards in the future.

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 $0.49 per share and as high as $4.20 per share during the 12-month period ended February 29, 2020. On April 26, 2019, we effected a one-for-twenty reverse stock split of our issued and outstanding shares of Common Stock. As a result of the reverse split, each twenty pre-split shares of Common Stock outstanding automatically combined into one new share of Common Stock. The trading price of our Common Stock has been adjusted to reflect the reverse stock split as if it had occurred on January 1, 2018.

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 ourCommon Stock may be limited by trading volume.

During the 12-month period beginning on March 1, 2019 and ending on February 29, 2020, the average daily trading volume for our Common Stock on the NYSE American was approximately 395,000 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, 2019 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 Dr. Goldberg, CRG and Platinum-Montaur Life Sciences LLC ("Platinum-Montaur"), an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P. ("PPVA"), Platinum Partners Capital Opportunity Fund ("PPCO"), Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, "Platinum"). In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. The Company has considerable discretion over the extent of development project expenditures and has 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, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain or treat its impact, among others. A significant outbreak of COVID-19 or other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations, including our ability to obtain additional funding, if needed. 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, at a monthly base rent of approximately $3,000. The current lease term expires in June 2020 with an option to extend for an additional three years. In March 2020, we executed an amendment to extend the lease term through June 2023 at a monthly base rent of approximately $3,000. We believe this facility is 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, at a monthly base rent of approximately $26,000 during 2019. The current lease term expires in October 2022 with an option to extend for an additional five years. The Company does not intend to renew this lease. 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 14 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

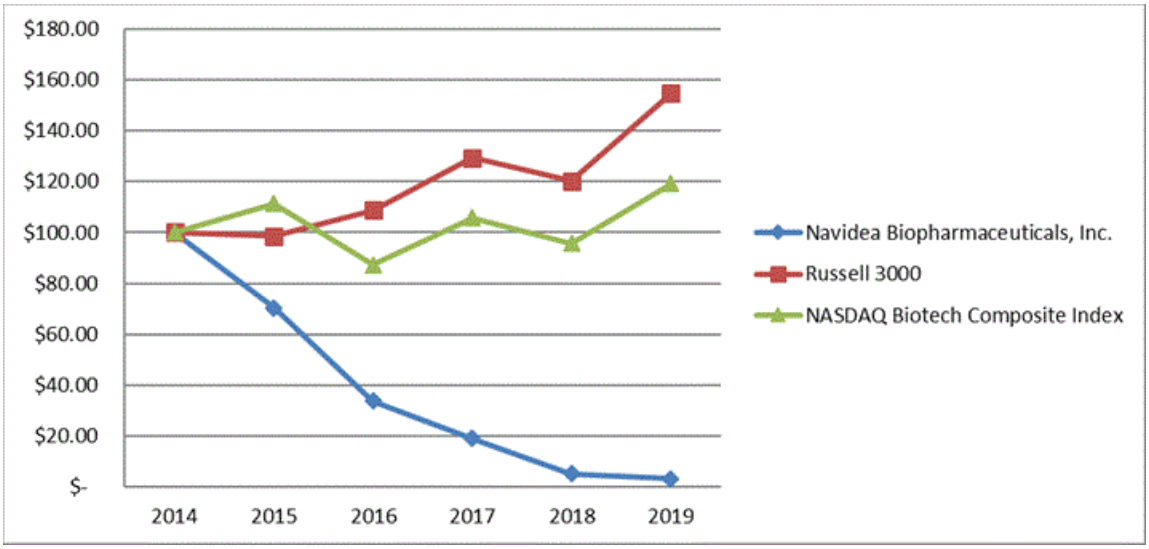
Our Common Stock trades on the NYSE American exchange under the trading symbol "NAVB." As of March 2, 2020, we had approximately 558 holders of Common Stock of record. There were no repurchases of our Common Stock during the year ended December 31, 2019.

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, 2014 through December 31, 2019. This graph assumes an investment in the Company's Common Stock and the indices of $100 on December 31, 2014 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 12/31/2014 in stock or index, including reinvestment of dividends.

	Cumulative Total Return as of December 31,					
	2014	2015	2016	2017	2018	2019
Navidea Biopharmaceuticals	$ 100.00	$ 70.37	$ 33.86	$ 19.05	$ 5.29	$ 3.33
Russell 3000	100.00	98.53	108.79	129.30	120.26	154.58
NASDAQ Biotechnology	100.00	111.42	87.26	105.64	95.79	119.17

Dividend Policy

We did not declare or pay any dividends and we do not currently intend to pay dividends in the foreseeable future. We currently expect to retain future earnings, if any, for the foreseeable future, to finance the growth and development of our business.

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 and commercialized by Navidea based on the platform.

As discussed previously under "Development of the Business," in March 2017 Navidea completed the sale to Cardinal Health 414 of all of its assets used in operating its business of developing, manufacturing and commercializing the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark in Canada, Mexico and the United States. Upon closing of the sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated and Cardinal Health 414 assumed responsibility for marketing Lymphoseek in those territories.

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 applications of our Manocept platform and all development programs undertaken by MT. See Note 17 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 both diagnostic and therapeutic applications of our Manocept platform, and Tc99m tilmanocept. We incurred approximately $5.3 million and $4.2 million in total on research and development activities during the years ended December 31, 2019 and 2018, 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)	**2019**	**2018**
Manocept Platform – Diagnostics	$ 3,105,196	$ 1,291,796
Manocept Platform – Therapeutics	542,822	1,203,419
Tc99m Tilmanocept	191,036	145,314

(a) Certain development program expenditures were offset by grant reimbursement revenues totaling $611,000 and $761,000 during the years ended December 31, 2019 and 2018, respectively.

We expect to continue the advancement of our efforts with our Manocept platform during 2020. We currently 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 2020 than in 2019. However, COVID-19 continues to spread globally and, as of March 2020, has spread to over 100 countries, including the United States. The spread of COVID-19 has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities and our supply chain. For example, the COVID-19 outbreak may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver clinical drug supplies on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations. The extent to which the recent global coronavirus pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain or treat its impact, among others. Any significant infectious disease outbreak, including the COVID-19 pandemic, could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations, including our ability to obtain additional funding, if needed.

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. 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

As discussed previously under "Item 1—Business—The Company," in March 2017, Navidea completed the sale to Cardinal Health 414 of all of its assets used in operating its business of developing, manufacturing and commercializing the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark in Canada, Mexico and the United States. In April 2018, the Company entered into an Amendment to the Purchase Agreement with Cardinal Health 414. 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 was 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. On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit.

We recorded a 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 sold to Cardinal Health 414 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, 2019 and 2018

Royalty Revenue. During 2019 and 2018, we recognized royalty revenue of $17,000 and $15,000, respectively, related to our license agreement with SpePharm in Europe.

License Revenue. During 2019, we recognized license revenue of $10,000 related to the sublicense of NAV4694 to Meilleur. 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.

Grant and Other Revenue. During 2019, we recognized $631,000 of grant and other revenue compared to $847,000 in 2018. Grant revenue during both periods was primarily related to SBIR grants from the NIH supporting Manocept development. Other revenue for 2019 and 2018 included $20,000 and $85,000, respectively, related to development work performed at the request of our European and Chinese marketing partners.

Research and Development Expenses. Research and development expenses increased $1.1 million, or 26%, to $5.3 million during 2019 from $4.2 million during 2018. The increase was primarily due to net increases in drug project expenses related to (i) increased Manocept development costs of $1.8 million, including increased clinical trial costs, manufacturing-related activities, and license fees; and (ii) increased Tc99m tilmanocept development costs of $46,000 including increased license fees offset by decreased manufacturing-related activities; offset by (iii) decreased therapeutics development costs of $661,000, including decreased research consulting, preclinical testing, regulatory consulting, and manufacturing-related activities; and (iv) decreased NAV4694 development costs of $34,000 due to reversal of certain previously accrued expenses. The net increase in research and development expenses also included decreased general office and travel expenses totaling $44,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $1.4 million, or 18%, to $6.3 million during 2019 from $7.7 million during 2018. The net decrease was primarily due to decreased compensation expense of $1.7 million, including termination costs related to the resignation of Dr. Goldberg of $1.1 million in 2018 coupled with decreased salaries and bonuses in 2019. The net decrease also included decreased investor relations services of $147,000 and decreased general office expenses and taxes, offset by increased losses on disposal of assets. These decreases were offset by increased legal and professional services of $435,000 including increased costs related to the Dr. Goldberg litigation offset by decreased costs related to the CRG litigation.

Other Income (Expense). Other income, net, was $18,000 during 2019 compared to other expense, net, of $5.3 million during 2018. We recorded a loss on extinguishment of the CRG debt of $5.3 million during 2018. Also during 2018, $153,000 of interest expense was compounded and added to the balance of our note payable to Platinum. During 2019 and 2018, we recognized interest income of $33,000 and $131,000, respectively. Interest income in 2018 was 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.

Gain on Discontinued Operations. We recorded a net gain related to the Amendment of $43,000 for 2018, including $54,000 of payments by Cardinal Health 414 to Navidea in excess of receivables recognized, offset by $11,000 in estimated taxes.

Liquidity and Capital Resources

Cash balances decreased $2.5 million to $1.0 million at December 31, 2019 from $3.5 million at December 31, 2018. The net decrease was primarily due cash used to fund our operations of $9.4 million, proceeds from a public offering and private equity placements of $7.1 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 used in operations was $9.4 million during 2019 compared to $4.3 million cash provided by operations during 2018.

Accounts and other receivables increased $880,000 to $901,000 at December 31, 2019 from $21,000 at December 31, 2018, primarily related to stock subscriptions of $812,000 that were received in January 2020 coupled with increased grant revenue receivable.

Prepaid expenses and other current assets decreased $332,000 to $967,000 at December 31, 2019 from $1.3 million at December 31, 2018. The decrease was primarily due to a net decrease in federal tax refunds receivable coupled with normal amortization of prepaid insurance, offset by the purchase of Tc99m tilmanocept to be used in clinical trials.

Accounts payable increased $687,000 to $1.1 million at December 31, 2019 from $425,000 at December 31, 2018, primarily driven by net increased payables due for Manocept development costs, legal and professional services, therapeutics development costs, and investor relations services. Accrued liabilities and other current liabilities decreased $366,000 to $2.1 million at December 31, 2019 from $2.5 million at December 31, 2018. Decreased accruals for termination of Dr. Goldberg and incentive-based compensation were offset by increased accruals for Manocept development costs. Our payable and accrual balances will continue to fluctuate, with planned increases in development activity related to the Manocept platform offset by decreased legal fees as we work to resolve our legal disputes.

Investing Activities. Investing activities provided $770,000 during 2019 compared to $954,000 provided during 2018. Investing activities during 2019 included maturities and sales of available-for-sale securities of $800,000, offset by patent and trademark costs of $57,000. 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.

Financing Activities. Financing activities provided $6.2 million during 2019 compared to $4.5 million used during 2018. The $6.2 million provided by financing activities in 2019 consisted primarily of proceeds from issuance of Common Stock of $7.1 million, offset by payment of Common Stock issuance costs of $572,000 and principal payments on the IPFS and First Insurance Funding notes payable of $359,000. 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.

Registered Offerings

On February 14, 2020, we executed an agreement with an investor to purchase 1,647,059 million shares of our Common Stock at a price of $0.85 per share for aggregate gross proceeds to Navidea of approximately $1.4 million. The offering was made pursuant to our shelf registration statement on Form S-3 (Registration No. 333-222092), which was declared effective by the Securities and Exchange Commission (the "SEC") on December 27, 2017, including the prospectus contained therein, as well as a prospectus supplement filed with the SEC on February 18, 2020. We intend to use the net proceeds from this offering to fund our research and development programs, including continued advancement of our two Phase 2b and Phase 3 clinical trials of Tc99m tilmanocept in patients with rheumatoid arthritis, and for general working capital purposes and other operating expenses. See Notes 2 and 15 to the accompanying consolidated financial statements.

Private Placements

On February 13, 2020, we executed a stock purchase agreement with John K. Scott, Jr. to purchase approximately 2.4 million shares of Common Stock for aggregate gross proceeds of approximately $2.0 million. We intend to use the net proceeds from this private placement to fund our research and development programs, including continued advancement of our two Phase 2b and Phase 3 clinical trials of Tc99m tilmanocept in patients with rheumatoid arthritis, and for general working capital purposes and other operating expenses. The securities offered and sold in the private placement to Mr. Scott have not been registered under the Securities Act of 1933, as amended, or state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from registration requirements. We have agreed to file a registration statement with the SEC covering the resale of the shares of Common Stock issued to Mr. Scott. See Notes 2 and 15 to the accompanying consolidated financial statements.

CRG Litigation

On February 13, 2020, the Company executed a binding term sheet to sell the judgment entered by the Court of Common Pleas of Franklin County, Ohio in favor of the Company in the amount of $4.3 million plus interest (the "Judgment"), for $4.2 million of proceeds to Navidea. The Company has the option, within 45 days of the sale, to repurchase the Judgment for a 10% premium. Such repurchase option may be in the form of Common Stock at a 10% discount to the then-current market price. See Notes 2, 12 and 14 to the accompanying consolidated financial statements.

Platinum Litigation

See Notes 2, 12 and 14 to the accompanying consolidated financial statements.

Goldberg Agreement and Litigation

See Notes 2, 10 and 14 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 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, the outcome of any pending litigation, and intellectual property protection.

We plan to focus our resources during 2020 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 we may need to seek additional financing in order to support our planned development programs.

We will continue to evaluate our timelines, 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 Dr. Goldberg, CRG and Platinum-Montaur. In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. The Company has considerable discretion over the extent of development project expenditures and has 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, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain or treat its impact, among others. A significant outbreak of COVID-19 or other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations, including our ability to obtain additional funding, if needed. 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, 2019, 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 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 18, 2020, are set forth at pages F-1 through F-32 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, 2019, 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, 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, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019 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, 2019, 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, 2019, 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.	64	Audit; Compensation, Nominating and Governance (Chair)
Adam D. Cutler	45	Audit (Chair); Compensation, Nominating and Governance
Jed. A. Latkin	45	—
Y. Michael Rice	55	Audit; Compensation, Nominating and Governance
S. Kathryn Rouan, Ph.D.	57	Compensation, Nominating and Governance

Director Qualifications

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

- *General Management.* Directors who have served in senior leadership positions 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 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, and Chief Scientific Officer of SAPVAX LLC for which she is a half-time employee to BioMotiv LLC. Dr Bruck is a member of the board of directors of Annovis Bio, Inc. (ANVS), a biotechnology company focused on development of medicines for neurodegenerative diseases. Dr. Bruck joined GlaxoSmithKline ("GSK") in 1985 to build GSK's HIV vaccine program. 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 holds a Ph.D. in biochemistry from the University of Brussels.

Directors whose terms continue until the 2022 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. Since July 2019, she has also served as a non-executive director of Viking Therapeutics, Inc. Dr. Rouan 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. From Decem ber 2013 to November 2018 she was also a member of the R&D Executive Management Team and R&D Governance Boards. 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. 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.

Information About our 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.	51	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.

Delinquent Section 16 Filings

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 SEC. 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, 2019, except for: (1) Drs. Bruck and Rouan, and Messrs. Cutler and Rice, who each had one late Form 4 filing related to stock issued as part of their annual director compensation; and (2) John K. Scott, Jr., who had two late Form 4 filings related to stock purchased in public and private placements.

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 14 meetings in the fiscal year ended December 31, 2019, 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. 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 2019 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. 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, 2019. 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 held two meetings in the fiscal year ended December 31, 2019. 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 60th 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 senior executive compensation levels at least annually. During the review process, the CNG Committee addresses the following questions:

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

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

The CNG Committee does not believe that our compensation policies and practices for our employees give rise to risks that are reasonably likely to have a material adverse effect on the Company. Our incentive-based compensation goals are generally tied to product development goals (e.g., clinical trial progress or regulatory milestones) or Company financial goals (e.g., budgeted expense targets or business partnerships). 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 August 8, 2019, approximately 70% of our stockholders voted in favor of the resolution relating to the compensation of our Named Executive Officers. The CNG Committee believes this vote affirmed our 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. The Company currently holds an advisory vote to approve the compensation of the Company's Named Executive Officers every two years. The two-year frequency of advisory "say-on-pay" votes will continue 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. Annually, the CNG Committee recommends 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 recommends or 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 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 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 January 1, 2019, by an annualized rate of 3.0%, the expected pay increase in 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 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.
Anthera Pharmaceuticals, Inc.
Aradigm Corporation
Argos Therapeutics, Inc.
CareDx, Inc.
Cascadian Therapeutics, Inc.
ContraFect Corporation
Curis, Inc.
CytoDyn, Inc.
Endocyte, Inc.
Genocea Biosciences, Inc.
iCad, Inc.
Idera Pharmaceuticals, Inc.
Immune Design Corporation
Innovation Pharmaceuticals, Inc.
Invitae Corporation
Invuity, Inc.
Lipocine, Inc.
Mirati Therapeutics, Inc.
Sonoma Pharmaceuticals, Inc.
Sorrento Therapeutics, Inc.
T2 Biosystems, Inc.
Utah Medical Products, 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. 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 60th 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 2019, 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 2019 compared to the approved salaries for fiscal 2018:

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

(a) The amount shown for fiscal 2019 and 2018 is the approved annual salary of the Named Executive Officer in effect at the end of each year. The actual amount paid to the Named Executive Officer during fiscal 2019 and 2018 is shown under "Salary" in the Summary Compensation table below.
(b) Due to the Company's financial difficulties, Named Executive Officers did not receive salary increases in 2019.

The following table shows the base salaries for the Named Executive Officers that were approved for fiscal 2020 compared to the approved salaries for fiscal 2019:

Named Executive Officer	Fiscal 2020 Base Salary	Fiscal 2019 Base Salary	Change
Jed A. Latkin	$ 475,000	$ 475,000	0.0%
Michael S. Rosol, Ph.D. (a)	225,000	205,000	9.8%

(a) In February 2020, the CNG Committee recommended, and the Board of Directors approved, an increase in Dr. Rosol's base salary effective February 1, 2020.

Short-Term Incentive Compensation. Our executive officers, along with our other 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 for our Named Executive Officers:

- 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 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.

For fiscal 2019, 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 2019 were as follows:

- Achievement of various business development goals, subject to a maximum 40% reduction of bonus if not achieved, including:
    - Enter into a RA commercialization partnership agreement with an established pharma company; and
    - Enter into a research agreement with an academic institution, foundation, or other clinical research firm to explore clinical feasibility and commercial opportunities for alternative image and therapeutic indications.
- Achievement of various clinical development goals, subject to a maximum 30% reduction of bonus if not achieved, including:
    - Advance commercialization program for RA imaging indications;
    - Secure opportunity with pharma to develop tilmanocept as a biomarker for disease indications;
    - Resolve a specified issue with tilmanocept synthesis; and
    - Explore the use with tilmanocept of agents other than Tc99m.
- Achievement of various financial development goals, subject to a maximum 20% reduction of bonus if not achieved, including:
    - Regain compliance with NYSE American listing standards; and
    - Adhere to the 2019 corporate budget to within 5% of budgeted operating expenses.
- Achievement of various intellectual property ("IP") goals, subject to a maximum 10% reduction of bonus if not achieved, including:
    - Develop an IP infrastructure to facilitate cohesive and coherent IP strategy; and
    - File four specified provisional patents.

For fiscal 2019, 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	75.0%	$ 356,250
Michael S. Rosol, Ph.D.	35.0%	71,750

On January 30, 2020, the Board of Directors determined the amounts to be awarded as 2019 bonuses to all employees other than the Named Executive Officers. The Board of Directors recognized the achievement of approximately 50% of 2019 bonus goals and thus awarded bonuses at 50% of target amounts for all employees other than the Named Executive Officers, to be paid 50% in stock immediately and 50% in cash at such time as the Company's financial position allows a cash payment. The Board of Directors also determined that Mr. Latkin's and Dr. Rosol's bonus awards will not be paid until certain of the 2019 bonus goals that were not achieved during 2019 are achieved.

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.

In January 2019, the Company awarded options to purchase 6,250 shares of Common Stock to Dr. Rosol in connection with his December 2018 appointment as Chief Medical Officer of Navidea. The options have an exercise price of $7.60 per share, and vest as to one-third of the options on January 2, 2019, July 2, 2019, and January 2, 2020. The options will expire on the tenth anniversary of the date of grant.

In February 2019, the Company awarded options to purchase 50,000 shares of Common Stock to Mr. Latkin in connection with his October 2018 appointment as Chief Executive Officer, Chief Operating Officer, and Chief Financial Officer of Navidea. The options were awarded with the following terms: (1) 16,667 options with an exercise price of $3.00 will be exercisable on or after February 7, 2019, so long as the closing price of the underlying Common Stock equals or exceeds $10.00 per share; (2) 16,667 options with an exercise price of $6.00 will be exercisable on or after December 31, 2019, so long as the closing price of the underlying Common Stock equals or exceeds $14.00 per share; and (3) 16,666 options with an exercise price of $10.00 will be exercisable on or after December 31, 2020, so long as the closing price of the underlying Common Stock equals or exceeds $20.00 per share. The options will expire on the tenth anniversary of the date of grant.

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 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.

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, with automatic one-year renewals unless terminated earlier pursuant to the terms of the agreement. The employment agreement provides for an annual base salary of $475,000. For the calendar year ending December 31, 2019, 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, 2019, or at any other time, an officer or employee of the Company.

No director who served on the CNG Committee during 2019 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 2019.

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 2019

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	2019	$ 475,000	$ —	$ 81,200	$ (b)	$ 5,600	$ 561,800
Chief Executive Officer,	2018	362,500	—	—	271,875	5,500	639,875
Chief Operating Officer and	2017	316,458	—	125,833	366,653	5,429	814,373
Chief Financial Officer							
Michael S. Rosol, Ph.D. (d)	2019	$ 205,000	$ —	$ 6,316	$ (b)	$ 2,915	$ 214,231
Chief Medical Officer	2018	8,542	—	—	2,949	—	11,491
	2017	—	—	—	—	—	—

(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). The Board of Directors has not yet determined the 2019 non-equity incentive plan amounts for the Named Executive Officers. We will provide updated disclosure on a Current Report on Form 8-K, as required by applicable SEC rules once the amounts are approved.
(c) Amount represents the Company contribution to the 401(k) plan on behalf of our Named Executive Officers.
(d) Dr. Rosol commenced employment with the Company effective December 17, 2018.

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 2019, 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 $561,800;
- The median of the annual total compensation of all of our employees, excluding the Chief Executive Officer, was $85,922; and
- The ratio of the annual total compensation of our CEO to the median of the annual total compensation of all other employees was 6.5 to 1.

In determining the pay ratio information provided above, we first identified our median employee for 2019 by using the following methodology:

- We selected December 31, 2019 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.

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, 2019 and a stock price of $1.26, our closing stock price on December 31, 2019.

Jed A. Latkin

	For Cause	Resignation	Death	Disability	Good Reason or Without Cause	End of Term	Change in Control
Cash payments:							
Severance (a)	$ —	$ —	$ —	$ —	$ 712,500	$ —	$ 1,959,375
Accrued bonus (b)	—	—	—	—	(b)	—	(b)
Disability supplement (c)	—	—	—	231,500	—	—	—
Paid time off (d)	9,135	9,135	9,135	9,135	9,135	9,135	9,135
2019 401(k) match (e)	5,600	5,600	5,600	5,600	5,600	5,600	5,600
Continuation of benefits (f)	—	—	548	548	—	—	—
Stock option vesting acceleration (g)	—	—	—	—	—	—	—
Total	$ 14,735	$ 14,735	$ 15,283	$ 246,783	$ 727,235	$ 14,735	$ 1,974,110

(a) Severance amounts are pursuant to Mr. Latkin's employment agreement.
(b) Amount represents accrued but unpaid bonus as of December 31, 2019. The Board of Directors has not yet determined the 2019 non-equity incentive plan amounts for the Named Executive Officers.
(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, 2019, the Company's short-term disability insurance policy pays $250 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, 2019.
(e) Amount represents the value of 2,800 shares of Company stock which was accrued during 2019 as the Company's 401(k) matching contribution but was unissued as of December 31, 2019.
(f) Amount represents 12 months of dental insurance premiums at rates in effect at December 31, 2019.
(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 $1.26, the closing price of the Company's stock on December 31, 2019, less the exercise price of the options. Amount does not include stock options with an exercise price higher than $1.26, the closing price of the Company's stock on December 31, 2019.

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, 2019 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 2019. 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 2019

Named Executive Officer	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards (a)		Estimated Future Payouts Under Equity Incentive Plan Awards		All Other Stock Awards: Number of Shares of Stock	All Other Option Awards: Number of Securities Underlying Options	Exercise Price of Option Awards	Grant Date Fair Value of Stock and Option Awards	
		Threshold	Maximum	Threshold	Maximum					
Jed A. Latkin	N/A	$ —	$ 356,250	—	—	—	—	$ —	$ —	(a)
	2/7/2019	—	—	—	—	—	16,667	3.00	33,101	(b)
	2/7/2019	—	—	—	—	—	16,667	6.00	26,169	(c)
	2/7/2019	—	—	—	—	—	16,666	10.00	21,935	(d)
Michael S. Rosol, Ph.D.	N/A	$ —	$ 71,750	—	—	—	—	—	$ —	(a)
	1/2/2019	—	—	—	—	—	6,250	7.60	6,316	(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 its discretion, awards the maximum cash bonus.

(b) These stock options vest when both of the following conditions have been met: Continued employment through February 7, 2019 and a closing market price of the Company's Common Stock of at least $10.00, and expire on the tenth anniversary of the date of grant.

(c) These stock options vest when both of the following conditions have been met: Continued employment through December 31, 2019 and a closing market price of the Company's Common Stock of at least $14.00, and expire on the tenth anniversary of the date of grant.

(d) These stock options vest when both of the following conditions have been met: Continued employment through December 31, 2020 and a closing market price of the Company's Common Stock of at least $20.00, and expire on the tenth anniversary of the date of grant.

(e) These stock options vest as to one-third of the options on January 2, 2019, July 2, 2019 and January 2, 2020, and expire on the tenth anniversary of the date of grant.

Outstanding Equity Awards

The following table presents certain information concerning outstanding equity awards held by the Named Executive Officers as of December 31, 2019.

Outstanding Equity Awards Table at Fiscal 2019 Year-End

	Option Awards					Stock Awards				
	Number of Securities Underlying Unexercised Options (#)							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	Market Value of Shares of Stock that Have Not Vested	Number of Unearned Shares	Market Value of Unearned Shares	Note
Jed A. Latkin	2,250	—	$ 30.00	4/20/2026	(a)					
	1,000	—	$ 20.00	10/14/2026	(b)					
	—	16,667	$ 13.00	5/4/2027	(c)					
	—	16,667	$ 15.00	5/4/2027	(d)					
	—	16,666	$ 20.00	5/4/2027	(e)					
	—	16,667	$ 3.00	2/7/2029	(f)					
	—	16,667	$ 6.00	2/7/2029	(g)					
	—	16,666	$ 10.00	2/7/2029	(h)					
Michael S. Rosol, Ph.D. (h)	4,167	2,083	$ 7.60	1/2/2029	(i)					

(a) Options were granted April 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 October 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 May 4, 2017 and vest 100% when both of the following conditions have been met: Continued employment through May 4, 2017 and a closing market price of the Company's Common Stock of at least $17.00.
(d) Options were granted May 4, 2017 and vest 100% when both of the following conditions have been met: Continued employment through December 31, 2017 and a closing market price of the Company's Common Stock of at least $20.00.
(e) Options were granted May 4, 2017 and vest 100% when both of the following conditions have been met: Continued employment through December 31, 2018 and a closing market price of the Company's Common Stock of at least $25.00.
(f) Options were granted February 7, 2019 and vest 100% when both of the following conditions have been met: Continued employment through February 7, 2019 and a closing market price of the Company's Common Stock of at least $10.00.
(g) Options were granted February 7, 2019 and vest 100% when both of the following conditions have been met: Continued employment through December 31, 2019 and a closing market price of the Company's Common Stock of at least $14.00.
(h) Options were granted February 7, 2019 and vest 100% when both of the following conditions have been met: Continued employment through December 31, 2020 and a closing market price of the Company's Common Stock of at least $20.00.
(i) Options were granted January 2, 2019 and vest as to one-third on January 2, 2019, July 2, 2019 and January 2, 2020.

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 2019.

Options Exercised and Stock Vested Table for Fiscal 2019

	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 S. Rosol, Ph.D.	—	$ —	—	$ —	

Compensation of Non-Employee Directors

Each non-employee director received an annual cash retainer of $50,000 during the fiscal year ended December 31, 2019. The Chair of the Company's Board of Directors received an additional annual retainer of $30,000. Audit and CNG Committee members received an annual retainer of $2,500 for each committee on which they served. The Chair of the Audit Committee received an additional annual retainer of $7,500, and the Chair of the CNG Committee received an additional annual retainer of $5,000 for their services in those capacities during 2019. We also reimbursed non-employee directors for travel expenses for meetings attended during 2019.

Each non-employee director also received 2,500 shares of restricted stock and 2,500 options to purchase stock at $5.00 per share during 2019 as a part of the Company's annual stock incentive grants, in accordance with the provisions of the Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan. The restricted stock and stock options granted will vest on the first anniversary of the date of grant.

The aggregate number of equity awards outstanding at January 31, 2020 for each Director is set forth in the footnotes to the beneficial ownership table provided in the section entitled "Principal Stockholders." 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, 2019.

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.	$ 60,000	$ 4,382	$ 7,465	$ —	$ 71,847
Adam D. Cutler (f)	62,500	6,153	13,150	—	81,803
Y. Michael Rice	85,000	4,382	7,465	—	96,847
S. Kathryn Rouan, Ph.D. (f)	52,500	6,153	13,150	—	71,803

(a) Amount represents fees earned during the fiscal year ended December 31, 2019 (i.e., the year to which the service relates). Quarterly retainers are paid during the quarter following the quarter in which they are earned.

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

(c) During the year ended December 31, 2019, the non-employee directors were awarded an aggregate of 15,000 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, 2019, the non-employee directors held an aggregate of 22,500 options to purchase Common Stock. Mr. Rice held 7,500 options, and Dr. Bruck, Mr. Cutler, and Dr. Rouan each held 5,000 options to purchase shares of Common Stock.

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

(e) During the year ended December 31, 2019, the non-employee directors were issued an aggregate of 15,000 shares of restricted stock which vest as to 100% of the shares on the first anniversary of the date of grant. At December 31, 2019, the non-employee directors held an aggregate of 15,000 shares of unvested restricted stock. Mr. Cutler and Dr. Rouan each held 5,000 shares of unvested restricted stock, and Mr. Rice and Dr. Bruck each held 2,500 shares of unvested restricted stock.

(f) 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.

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, 2019, 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]	238,470	$ 17.38	14,664,528
Equity compensation plans not approved by security holders	—	—	—
Total	238,470	$ 17.38	14,664,528

(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 207,890 issued under the 2014 Plan and 30,580 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 29, 2020, 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.	12,550	(a)	—	(i)
Adam D. Cutler	10,000	(b)	—	(i)
Jed A. Latkin	21,200	(c)	—	(i)
Y. Michael Rice	15,000	(d)	—	(i)
Michael S. Rosol, Ph.D.	6,250	(e)	—	(i)
S. Kathryn Rouan, Ph.D.	13,350	(f)	—	(i)
All directors and executive officers as a group (6 persons)	78,350	(g)(j)	—	(i)
John K. Scott, Jr.	5,678,772	(h)	27.8%	

(*) 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 29, 2020, plus the number of shares the person has the right to acquire within 60 days of February 29, 2020.

(a) This amount includes 5,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 2,500 shares of unvested restricted stock and 2,500 shares issuable upon exercise of options which are not exercisable within 60 days.

(b) This amount includes 5,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 2,500 shares of unvested restricted stock and 2,500 shares issuable upon exercise of options which are not exercisable within 60 days.

(c) This amount includes 3,250 shares issuable upon exercise of options which are exercisable within 60 days and 1,542 shares in Mr. Latkin's account in the 401(k) Plan, but does not include 200,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(d) This amount includes 7,500 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 2,500 shares of unvested restricted stock and 2,500 shares issuable upon exercise of options which are not exercisable within 60 days.

(e) This amount includes 6,250 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 25,000 shares issuable upon exercise of options which are not exercisable within 60 days.

(f) This amount includes 5,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 2,500 shares of unvested restricted stock and 2,500 shares issuable upon exercise of options which are not exercisable within 60 days.

(g) This amount includes 32,000 shares issuable upon exercise of options which are exercisable within 60 days, and 1,542 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 10,000 shares of unvested restricted stock and 235,000 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 12,827 shares of Common Stock.

(h) The number of shares beneficially owned is based on a Form 4 filed by John K. Scott, Jr. with the SEC on February 19, 2020, and has been reduced by 2,373,529 shares to be issued pursuant to a February 2020 Stock Purchase Agreement, which shares have not yet been issued as of February 29, 2020. The address of John K. Scott, Jr. is 5251 DTC Parkway, Suite 285, Greenwood Village, CO 80111.

(i) Less than one percent.

(j) The address of all directors and executive officers is c/o Navidea Biopharmaceuticals, Inc., 4995 Bradenton Avenue, Suite 240, Dublin, OH 43017.

All of our employees and directors, or any of their designees, are prohibited from (i) purchasing financial instruments (including prepaid variable forward contracts, equity swaps, collars, and exchange funds), or (ii) otherwise engaging in transactions (including "short sales" and arrangements involving a non-recourse pledge of securities), that hedge or offset, or are designed to hedge or offset, any decrease in the market value of shares of our common stock granted to such employee or director, or any of their designees, as part of their compensation, or held (directly or indirectly) by such employee or director, or any of their designees.

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 related persons, even though they may not have been related persons at the time the Company entered into the transactions described below.

Dr. Goldberg and Platinum

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

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to PPCO an aggregate of approximately $7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which were transferred by Platinum-Montaur to PPCO.

In November 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York (the "New York Supreme Court"), 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 subsequently removed to the United States District Court for the Southern District of New York (the "District Court"). 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. The Second Circuit held oral argument in this matter on September 5, 2019. On November 25, 2019, the Second Circuit issued a decision which remanded the case to the District Court for further consideration of whether the District Court had jurisdiction over the case following removal from the New York Supreme Court. The Second Circuit did not address the merits of Platinum-Montaur's allegations against Navidea. By agreement of the parties, the case has now been remanded from the District Court to the New York Supreme Court. A preliminary conference is set for April 28, 2020.

Goldberg Litigation

In August 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 Goldberg Agreement, with the intent of entering into one or more additional Definitive Agreements, which set forth the terms of the separation from service. Among other things, the Goldberg Agreement provided that Dr. Goldberg would be entitled to 1,175,000 shares of our Common Stock, representing in part payment of accrued bonuses and payment of the balance of the Platinum debt. A portion of the 1,175,000 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 debt to a party other than Dr. Goldberg. Further, the Goldberg Agreement provided that the Company's subsidiary, MT, would 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. In November 2018, the Company issued 925,000 shares of our Common Stock to Dr. Goldberg, 250,000 of which were placed in escrow in accordance with the Goldberg Agreement.

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 in accordance with its terms, effective March 1, 2019, due to MT's insolvency. On February 20, 2019, the MT Board 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 Jed A. Latkin to serve as President and Chief Executive Officer of MT.

New York Litigation Involving Dr. Goldberg

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the United States District Court, Southern District of New York, alleging breach of the Goldberg 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 Goldberg Agreement is excused and that Navidea is entitled to terminate the Goldberg Agreement as a result of Dr. Goldberg's actions. On April 26, 2019, Navidea filed an amended complaint against Dr. Goldberg which added a claim for breach of fiduciary duty seeking damages related to certain actions Dr. Goldberg took while CEO of Navidea. On June 13, 2019, Dr. Goldberg answered the amended complaint and asserted counterclaims against Navidea and third-party claims against MT for breach of the Goldberg Agreement, wrongful termination, injunctive relief, and quantum meruit.

On December 26, 2019, the District Court ruled on several motions related to Navidea and MT and Dr. Goldberg that substantially limited the claims that Dr. Goldberg can pursue against Navidea and MT. Specifically, the District Court found that certain portions of Dr. Goldberg's counterclaims against Navidea and third-party claims against Macrophage failed to state a claim upon which relief can be granted. Specifically, the District Court ruled that actions taken by Navidea and MT, including reconstituting the MT Board, replacing Dr. Goldberg with Mr. Latkin as Chief Executive Officer of MT, terminating the sublicense between Navidea and MT, terminating certain research projects, and allowing MT intellectual property to revert back to Navidea, were not breaches of the Goldberg Agreement.

The District Court also rejected Dr. Goldberg's claim for wrongful termination as Chief Executive Officer of MT. In addition, the District Court found that Dr. Goldberg lacked standing to seek injunctive relief to force the removal of Dr. Claudine Bruck and Michael Rice from MT's Board of Directors, to invalidate all actions taken by the MT Board on or after November 29, 2018 (the date upon which Dr. Bruck and Mr. Rice were appointed by Navidea to the Board of MT), or to reinstate the terminated sublicense between Navidea and MT.

In addition, the District Court found Navidea's breach of fiduciary duty claim against Dr. Goldberg for conduct occurring more than three years prior to the filing of the complaint to be time-barred and that Dr. Goldberg is entitled to an advancement of attorneys' fees solely with respect to that claim. The parties are in the process of submitting the issue to the District Court for resolution on how much in fees Dr. Goldberg is owed under the District Court's order. On January 27, 2020, Dr. Goldberg filed a motion seeking additional advancement from Navidea for fees in connection with the New York Action and the Delaware Action. Navidea has opposed the motion.

On January 31, 2020, Goldberg filed a motion for leave to amend his complaint to add back in claims for breach of contract, breach of the implied covenant of good faith and fair dealing, quantum meruit and injunctive relief. Navidea and MT have opposed the motion. The discovery deadline in the New York Action is April 15, 2020.

Delaware Litigation Involving Dr. Goldberg

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 effect are void. On June 12, 2019, the Delaware Court found that Dr. Goldberg's actions were not authorized in compliance with the Delaware General Corporate Law. Specifically, the Delaware Court found that Dr. Goldberg's creation of a new subsidiary of MT and the purported assignment by Dr. Goldberg of MT's intellectual property to that subsidiary were void. The Delaware Court's ruling follows the order on May 23, 2019 in the case, in which it found Dr. Goldberg in contempt of its prior order holding Dr. Goldberg responsible for the payment of MT's fees and costs to cure the damages caused by Dr. Goldberg's contempt. MT's claims for breach of fiduciary duty and conversion against Dr. Goldberg remain pending. As a result of the Delaware Court's ruling and Navidea's prior termination of the sublicense between itself and MT, all of the intellectual property related to the Manocept platform is now directly controlled by Navidea. A trial on MT's claims against Goldberg for breach of fiduciary duty and conversion is presently scheduled for June 2020.

Derivative Action Involving Dr. Goldberg

On July 26, 2019, Dr. Goldberg served shareholder demands on the Boards of Navidea and MT repeating many of the claims made in the lawsuits described above. On or about November 20, 2019, Dr. Goldberg commenced a derivative action purportedly on behalf of MT in the District Court against Dr. Claudine Bruck, Y. Michael Rice, and Jed Latkin alleging a claim for breach of fiduciary duty based on the actions alleged in the demands. On January 30, 2020, a pre-motion conference was conducted before the District Court on an anticipated motion to dismiss and Dr. Goldberg has agreed to dismiss the derivative action in New York without prejudice and retains the ability to re-file the action in Delaware. See Note 14 to the accompanying consolidated financial statements.

Mr. Latkin and Platinum

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.

Macrophage Therapeutics, Inc. and Platinum

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 2019 and 2018, the largest aggregate amount of principal outstanding under the Platinum credit facility was $0 and $2.2 million, respectively. As of December 31, 2019 and 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.

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 2019 fiscal year, the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2019 fiscal year, and review of other SEC filings, were $306,034 (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 2018 fiscal year, the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for the 2018 fiscal year, and review of other SEC filings, were $275,850 (including direct engagement expenses).

Audit-Related Fees. No fees were billed by Marcum LLP for audit-related services for the 2019 or 2018 fiscal years.

Tax Fees. No fees were billed by Marcum LLP for tax-related services for the 2019 or 2018 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 2019 or 2018 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	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Navidea Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed April 26, 2019).
3.3	Amended and Restated By-Laws dated July 21, 1993, as amended July 18, 1995, May 30, 1996, July 26, 2007, and November 7, 2013 (filed as Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed November 12, 2013, and incorporated herein by reference).
4.1	Amended and Restated Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series B Cumulative Convertible Preferred Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 26, 2013).
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-3 filed December 31, 2019).
4.3	Description of Securities.*
4.4	Registration Rights Agreement, dated December 6, 2019, among Navidea Biopharmaceuticals, Inc. and the stockholders named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 11, 2019).
4.5	Form of Underwriter Warrants (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 17, 2019).
10.1	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).
10.2	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).
10.3	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).
10.4	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).
10.5	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).
10.6	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).
10.7	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). ^

Exhibit Number	Exhibit Description
10.8	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). ^
10.9	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).
10.10	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).
10.11	Security Agreement, dated as of May 15, 2015 among Navidea Biopharmaceuticals, Inc., as borrower, Macrophage Therapeutics, Inc. as guarantor, and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as lenders, and Capital Royalty Partners II L.P., as control agent (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 15, 2015).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16	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).
10.17	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).
10.18	Series NN 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).
10.19	Series NN 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).
10.20	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).
10.21	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).
10.22	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).

Exhibit Number	Exhibit Description
10.23	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).^
10.24	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).
10.25	Stock Purchase Agreement, dated March 22, 2019, between Navidea Biopharmaceuticals, Inc. and John K. Scott, Jr. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed May 9, 2019).
10.26	Stock Purchase Agreement, dated December 6, 2019, among Navidea Biopharmaceuticals, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 11, 2019).
10.27	Stock Purchase Agreement, effective February 14, 2020, by and between Navidea Biopharmaceuticals, Inc. and Keystone Capital Partners, LLC.*
10.28	Stock Purchase Agreement, effective February 14, 2020, by and between Navidea Biopharmaceuticals, Inc. and John K. Scott.*
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 18, 2020

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 18, 2020
*/s/ Y. Michael Rice** Y. Michael Rice	Chair, Director	March 18, 2020
*/s/ Claudine Bruck** Claudine Bruck, Ph.D.	Director	March 18, 2020
*/s/ Adam D. Cutler** Adam D. Cutler	Director	March 18, 2020
*/s/ S. Kathryn Rouan** S. Kathryn Rouan, Ph.D.	Director	March 18, 2020

*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, 2019 and 2018
and for Each of the
Two Years in the Period Ended
December 31, 2019

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, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' (deficit) equity and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Adoption of New Accounting Standards

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU No. 2016-02, *Leases (Topic 842), as amended*, effective January 1, 2019, using the cumulative-effect adjustment transition method.

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 a working capital deficiency, 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 18, 2020

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,047,159	$ 3,475,881
Available-for-sale securities	—	799,270
Accounts and other receivables	901,339	21,151
Prepaid expenses and other	967,285	1,299,454
Total current assets	2,915,783	5,595,756
Property and equipment	1,207,537	1,251,185
Less accumulated depreciation and amortization	1,177,327	1,089,013
Property and equipment, net	30,210	162,172
Right-of-use lease assets	404,594	—
Less accumulated amortization	122,906	—
Right-of-use lease assets, net	281,688	—
License agreements, patents and trademarks	478,672	480,404
Less accumulated amortization	93,259	51,912
License agreements, patents and trademarks, net	385,413	428,492
Other assets	537,812	835,107
Total assets	$ 4,150,906	$ 7,021,527
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 1,112,069	$ 424,718
Accrued liabilities and other	2,150,974	2,517,047
Notes payable	305,955	316,074
Lease liabilities, current	250,553	—
Terminated lease liability, current	—	120,679
Total current liabilities	3,819,551	3,378,518
Lease liabilities	512,344	—
Terminated lease liability	—	468,494
Deferred revenue	700,000	700,000
Other liabilities	—	64,055
Total liabilities	5,031,895	4,611,067
Commitments and contingencies (Note 14)		
Stockholders' (deficit) equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at December 31, 2019 and 2018	—	—
Common stock; $.001 par value; 300,000,000 shares authorized; 19,234,960 and 10,019,535 shares issued and outstanding at December 31, 2019 and 2018, respectively	210,232	200,391
Common stock subscribed; $.001 par value, 902,162 and 0 shares subscribed at December 31, 2019 and 2018, respectively	902	—
Additional paid-in capital	345,847,676	338,265,383
Accumulated deficit	(347,671,102)	(336,722,905)
Accumulated other comprehensive loss	—	(730)
Total Navidea stockholders' (deficit) equity	(1,612,292)	1,742,139
Noncontrolling interest	731,303	668,321
Total stockholders' (deficit) equity	(880,989)	2,410,460
Total liabilities and stockholders' (deficit) equity	$ 4,150,906	$ 7,021,527

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Operations

	Years Ended December 31,	
	2019	**2018**
Revenue:		
Royalty revenue	$ 16,665	$ 15,347
License revenue	9,953	307,174
Grant and other revenue	631,208	846,830
Total revenue	657,826	1,169,351
Cost of revenue	6,667	96,636
Gross profit	651,159	1,072,715
Operating expenses:		
Research and development	5,338,267	4,221,881
Selling, general and administrative	6,275,409	7,698,135
Total operating expenses	11,613,676	11,920,016
Loss from operations	(10,962,517)	(10,847,301)
Other income (expense):		
Interest income (expense), net	25,288	(30,799)
Loss on extinguishment of debt	—	(5,291,616)
Other (expense) income, net	(7,613)	1,145
Total other income (expense), net	17,675	(5,321,270)
Loss before income taxes	(10,944,842)	(16,168,571)
(Provision for) benefit from income taxes	(707)	9,753
Loss from continuing operations	(10,945,549)	(16,158,818)
Discontinued operations, net of tax effect:		
(Loss) income from discontinued operations	(2,665)	1,449
Gain on sale	—	43,053
Net loss	(10,948,214)	(16,114,316)
Less loss attributable to noncontrolling interest	(17)	(379)
Net loss attributable to common stockholders	$ (10,948,197)	$ (16,113,937)
Loss per common share (basic and diluted):		
Continuing operations	$ (0.76)	$ (1.90)
Discontinued operations	$ —	$ 0.01
Attributable to common stockholders	$ (0.76)	$ (1.89)
Weighted average shares outstanding (basic and diluted)	14,393,360	8,526,767

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Comprehensive Loss

	Years Ended December 31,	
	2019	**2018**
Net loss	$ (10,948,214)	$ (16,114,316)
Unrealized gain on available-for-sale securities	730	1,666
Comprehensive loss	$ (10,947,484)	$ (16,112,650)

See accompanying notes to consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Stockholders' (Deficit) Equity

	Common Stock		Common Stock Subscribed		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non-controlling Interest	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount					
Balance, January 1, 2018	8,110,332	$ 162,207	—	$ —	$ 331,128,787	$ (319,908,968)	$ (2,396)	$ 668,700	$ 12,048,330
Impact of adoption of ASC Topic 606	—	—	—	—	—	(700,000)	—	—	(700,000)
Issued stock in payment of employee bonuses	55,938	1,118	—	—	315,784	—	—	—	316,902
Issued restricted stock	10,000	200	—	—	—	—	—	—	200
Cancelled forfeited restricted stock	(2,500)	(50)	—	—	50	—	—	—	—
Issued stock to 401(k) plan	4,734	95	—	—	35,885	—	—	—	35,980
Issued stock pursuant to private placement	916,031	18,321	—	—	2,981,679	—	—	—	3,000,000
Issued stock pursuant to termination agreement	925,000	18,500	—	—	3,496,500	—	—	—	3,515,000
Stock compensation expense	—	—	—	—	306,698	—	—	—	306,698
Comprehensive loss:			—	—					
Net loss	—	—	—	—	—	(16,113,937)	—	(379)	(16,114,316)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	1,666	—	1,666
Total comprehensive loss	—	—	—	—	—	—	—	—	(16,112,650)
Balance, December 31, 2018	10,019,535	$ 200,391	—	—	$ 338,265,383	$ (336,722,905)	$ (730)	$ 668,321	$ 2,410,460
Issued restricted stock	15,000	300	—	—	—	—	—	—	300
Issued stock pursuant to private placements	1,173,411	1,513	—	—	1,088,487	—	—	—	1,090,000
Adjustments related to reverse stock split	(1,114)	—	—	—	(3,385)	—	—	—	(3,385)
Issued stock to 401(k) plan	8,128	8	—	—	19,580	—	—	—	19,588
Issued stock pursuant to public offering, net of offering costs of $841,559	8,000,000	8,000	—	—	5,158,441	—	—	—	5,166,441
Value of warrants issued in connection with public offering	—	—	—	—	261,288	—	—	—	261,288
Issued stock in payment of services	20,000	20	—	—	14,780	—	—	—	14,800
Stock subscribed in connection with private placement	—	—	902,162	902	811,044	—	—	—	811,946
Change in estimated fair value of MT warrants	—	—	—	—	—	—	—	63,000	63,000
Stock compensation expense	—	—	—	—	232,058	—	—	—	232,058
Comprehensive loss:									
Net loss	—	—	—	—	—	(10,948,197)	—	(17)	(10,948,214)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	730	—	730
Total comprehensive loss	—	—	—	—	—	—	—	—	(10,947,484)
Balance, December 31, 2019	19,234,960	$ 210,232	902,162	$ 902	$ 345,847,676	$ (347,671,102)	$ —	$ 731,303	$ (880,989)

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (10,948,214)	$ (16,114,316)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization of property and equipment	103,165	120,721
Amortization of license agreements, patents and trademarks	41,347	29,664
Loss on disposal and abandonment of patents and equipment	60,104	—
Compounded interest on long term debt	—	153,390
Stock compensation expense	232,058	306,698
Loss on extinguishment of debt	—	5,291,616
Value of stock issued to employees	—	616,902
Value of stock issued to 401(k) plan for employer matching contributions	19,588	35,980
Value of stock issued in payment for services	14,800	—
Changes in operating assets and liabilities:		
Accounts and other receivables	(68,242)	12,926,097
Prepaid expenses, right-of-use lease assets, and other assets	696,718	805,597
Accounts payable	687,351	(430,325)
Accrued, lease, and other liabilities	(195,989)	548,453
Deferred revenue	2,584	(15,037)
Net cash (used in) provided by operating activities	(9,354,730)	4,275,440
Cash flows from investing activities:		
Purchases of available-for-sale securities	—	(600,000)
Proceeds from sales of available-for-sale securities	400,000	200,000
Maturities of available-for-sale securities	400,000	1,400,000
Proceeds from disposal (payments for purchases) of equipment	27,125	(46,192)
Patent and trademark costs	(56,700)	—
Net cash provided by investing activities	770,425	953,808
Cash flows from financing activities:		
Proceeds from issuance of common stock	7,086,915	3,000,200
Payment of common stock issuance costs	(572,271)	—
Payment of debt-related costs	—	(7,153,000)
Principal payments on notes payable	(359,061)	(395,573)
Net cash provided by (used in) financing activities	6,155,583	(4,548,373)
Net (decrease) increase in cash	(2,428,722)	680,875
Cash and cash equivalents, beginning of period	3,475,881	2,795,006
Cash and cash equivalents, end of period	$ 1,047,159	$ 3,475,881

See accompanying notes to consolidated financial statements.

Notes to the Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

a. Organization and Nature of Operations: Navidea Biopharmaceuticals, Inc. ("Navidea," the "Company," or "we"), a Delaware Corporation (NYSE 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.

In July 2011, we established a European business unit, Navidea Biopharmaceuticals Limited, to address international development and commercialization needs for our technologies, including Tc99m tilmanocept. Navidea owns 100% of the outstanding shares of Navidea Biopharmaceuticals Limited.

In January 2015, Macrophage Therapeutics, Inc. ("MT") was formed specifically to explore immuno-therapeutic applications for the Manocept platform. Navidea owns 99.9% of the outstanding shares of MT.

In March 2017, pursuant to an Asset Purchase Agreement, the Company completed the 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 the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark in Canada, Mexico and the United States (the "Asset Sale"). Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the Lymphoseek business sold to Cardinal Health 414 as a discontinued operation. Cash flows associated with the operation of this business have been combined with operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows.

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.

On April 26, 2019, the Company effected a one-for-twenty reverse stock split of its issued and outstanding shares of its common stock, par value $.001 per share ("Common Stock"). As a result of the reverse split, each twenty pre-split shares of Common Stock outstanding automatically combined into one new share of Common Stock. The number of outstanding shares of Common Stock was reduced from approximately 201.0 million to approximately 10.1 million shares. The authorized number of shares of Common Stock was not reduced and remains at 300.0 million. The par value of the Company's Common Stock remained unchanged at $0.001 per share after the reverse split. Our consolidated balance sheets, statements of operations, statements of stockholders' (deficit) equity, and accompanying notes to the financial statements have been restated, as required, for all periods presented to reflect the reverse stock split as if it had occurred on January 1, 2018. Our consolidated statements of cash flows were not impacted by the reverse stock split.

b. Principles of Consolidation: Our consolidated financial statements include the accounts of Navidea and our wholly-owned subsidiary, Navidea Biopharmaceuticals Limited, as well as those of our majority-owned subsidiary, MT. All significant inter-company accounts were eliminated in consolidation.

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

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

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

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

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

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. In determining the appropriate levels, we perform a detailed analysis of the assets and liabilities whose fair value is measured on a recurring basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3. See Note 5.

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

(1) Cash and cash equivalents, available-for-sale securities, accounts and other receivables, and accounts payable: The carrying amounts approximate fair value because of the short maturity of these instruments.

(2) Notes payable: The carrying value of our debt at December 31, 2019 and 2018 primarily consisted of the face amount of the notes plus accrued interest. At December 31, 2019 and 2018, the fair value of our notes payable was approximately $306,000 and $316,000, respectively, both amounts equal to the carrying value of the notes payable. See Notes 5 and 12.

(3) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. Derivative liabilities totaling $0 and $63,000 as of December 31, 2019 and 2018, respectively, were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of December 31, 2019 and 2018 included volatility, a risk-free rate and expected dividends. In addition, we considered non-performance risk and determined that such risk is minimal. Unrealized gains and losses on the derivatives are classified in other expenses as a change in the fair value of financial instruments in the statements of operations. See Note 5.

(4) Warrants: In June 2019, in connection with an underwriting agreement (the "Underwriting Agreement") between the Company and H.C. Wainwright & Co., LLC (the "Underwriter") related to a public offering, the Company issued to the Underwriter warrants to purchase 600,000 shares of Common Stock, representing 7.5% of the aggregate number of shares of Common Stock sold in the offering (the "Series OO Warrants"). The Series OO Warrants had an estimated fair value of $261,000 at the date of issuance, which was recorded in additional paid-in capital as a reduction of the gross proceeds raised in the public offering. The assumptions used to calculate fair value of the Series OO Warrants included volatility of 88.6%, a risk-free rate of 1.8% and expected dividends of $0. See Note 15(b).

e. Stock-Based Compensation: At December 31, 2019, we had instruments outstanding under two stock-based compensation plans; the Fourth Amended and Restated 2002 Stock Incentive Plan (the "2002 Plan") and the Amended and Restated 2014 Stock Incentive Plan (the "2014 Plan"). Currently, under the 2014 Plan, we may grant incentive stock options, nonqualified stock options, and restricted stock awards to full-time employees and directors, and nonqualified stock options and restricted stock awards may be granted to our consultants and agents. Total shares authorized under each plan are 12 million shares and 15 million shares, respectively. Although instruments are still outstanding under the 2002 Plan, the plan has expired and no new grants may be made from it. Under both plans, the exercise price of each option is greater than or equal to the closing market price of our Common Stock on the date of the grant.

Stock options granted under the 2002 Plan and the 2014 Plan generally vest on an annual basis over one to four years. Outstanding stock options under the plans, if not exercised, generally expire ten years from their date of grant or up to 90 days following the date of an optionee's separation from employment with the Company. We issue new shares of our Common Stock upon exercise of stock options.

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. 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. 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.

Expected volatilities are based on the Company's historical volatility, which management believes represents the most accurate basis for estimating expected future volatility under the current circumstances. Navidea uses historical data to estimate forfeiture rates. The expected term of stock options granted is based on the vesting period and the contractual life of the options. The risk-free rate is based on the U.S. Treasury yield in effect at the time of the grant. The assumptions used to calculate the fair value of stock option awards granted during the years ended December 31, 2019 and 2018 are noted in the following table:

	2019	2018
Expected volatility	76% - 93%	64% - 76%
Weighted-average volatility	86%	69%
Expected forfeiture rate	15.1% - 15.5%	18.7%
Expected term (in years)	3.5 - 6.0	5.5 - 6.0
Risk-free rate	2.4% - 2.5%	2.6% - 2.7%
Expected dividends	—	—

The portion of the fair value of stock-based awards that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. Restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award. Restricted stock may vest based on the passage of time, or upon occurrence of a specific event or achievement of goals as defined in the grant agreements. In such cases, we record compensation expense related to grants of restricted stock based on management's estimates of the probable dates of the vesting events. Stock-based awards that do not vest because the requisite service period is not met prior to termination result in reversal of previously recognized compensation cost. See Note 6.

f. Cash and Cash Equivalents: Cash equivalents are highly liquid instruments such as U.S. Treasury bills, bank certificates of deposit, corporate commercial paper and money market funds which have maturities of less than three months from the date of purchase.

g. Available-for-Sale Securities: Available-for-sale securities are liquid instruments such as U.S. Treasury bills, bank certificates of deposit, corporate commercial paper and money market funds which have maturities of three months or more from the date of purchase.

h. Accounts and Other Receivables: Accounts and other receivables are recorded net of an allowance for doubtful accounts. We estimate an allowance for doubtful accounts based on a review and assessment of specific accounts and other receivables and write off accounts against the allowance account when deemed uncollectible. See Note 8.

i. Property and Equipment: Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is generally computed using the straight-line method over the estimated useful lives of the depreciable assets. Depreciation and amortization related to equipment under capital leases and leasehold improvements is recognized over the shorter of the estimated useful life of the leased asset or the term of the lease. Maintenance and repairs are charged to expense as incurred, while renewals and improvements are capitalized. See Note 9.

j. Intangible Assets: Intangible assets consist primarily of license agreements, and patent and trademark costs. Intangible assets are stated at cost, less accumulated amortization. License agreements and patent costs are amortized using the straight-line method over the estimated useful lives of the license agreements and patents of approximately 5 to 15 years. Patent application costs are deferred pending the outcome of patent applications. Costs associated with unsuccessful patent applications and abandoned intellectual property are expensed when determined to have no recoverable value. We evaluate the potential alternative uses of all intangible assets, as well as the recoverability of the carrying values of intangible assets, on a recurring basis. During 2019 and 2018, we capitalized patent and trademark costs of $57,000 and $0, respectively. During 2019 and 2018, we abandoned patents with previously-capitalized patent costs of $58,000 and $0, respectively.

k. Impairment or Disposal of Long-Lived Assets: Long-lived assets and certain identifiable intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. No impairment was recognized during the years ended December 31, 2019 or 2018. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

l. Leases: All of our leases are operating leases and are included in right-of-use lease assets, current lease liabilities and noncurrent lease liabilities on our consolidated balance sheets. These assets and liabilities are recognized at the commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates or implicit rates, when readily determinable. Short-term operating leases which have an initial term of 12 months or less are not recorded on the consolidated balance sheets. Lease expense for operating leases is recognized on a straight-line basis over the lease term, and is included in selling, general and administrative expenses on our consolidated statements of operations. See Note 13.

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

n. Revenue Recognition: 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. See Note 4.

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

p. Income Taxes: Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at December 31, 2019 and 2018.

Current accounting standards include guidance on the accounting for uncertainty in income taxes recognized in the financial statements. Such standards also prescribe a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company believes that the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of December 31, 2019 or 2018 and we do not expect any significant changes in the next twelve months. Should we need to accrue interest or penalties on uncertain tax positions, we would recognize the interest as interest expense and the penalties as a selling, general and administrative expense. As of December 31, 2019, tax years 2016-2019 remained subject to examination by federal and state tax authorities. See Note 16.

q. Recently Adopted Accounting Standards: In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 requires the recognition of right-of-use lease assets and lease liabilities by lessees for those leases classified as operating leases under previous U.S. GAAP. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term.

In July 2018, the FASB issued ASU No. 2018-10,*Codification Improvements to Topic 842, Leases*, and ASU No. 2018-11, *Targeted Improvements to Topic 842, Leases*. ASU 2018-10 updates Topic 842 in order to clarify narrow aspects of the guidance issued in ASU 2016-02*Leases (Topic 842)*. ASU 2018-11 provides entities with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current U.S. GAAP (Topic 840, *Leases*). An entity that elects this transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments in ASU 2018-10 and ASU 2018-11 are effective when ASU 2016-02 is effective, for fiscal years beginning after December 15, 2018.

The Company adopted ASU 2016-02, ASU 2018-10 and ASU 2018-11 effective January 1, 2019 using the cumulative-effect adjustment transition method, which applies the provisions of the standard at the effective date without adjusting the comparative periods presented. Related to the adoption of these standards, the Company made a short-term lease accounting policy election allowing lessees to not recognize right-of-use assets and liabilities for leases with an initial term of 12 months or less.

The adoption of ASU 2016-02 resulted in the recognition of operating lease right-of-use assets and related lease liabilities of approximately $407,000 on the consolidated balance sheet as of January 1, 2019 related to our leases that were previously classified as operating leases, primarily for office space. The adoption of ASU 2016-02 did not materially impact our operating results or liquidity. Disclosures related to the amount, timing and uncertainty of cash flows arising from leases are included in Note 13.

In June 2018, the FASB issued ASU No. 2018-07,*Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards, and that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, *Revenue from Contracts with Customers.* ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The adoption of ASU 2018-07 did not have a significant impact on our consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-09,*Codification Improvements*. ASU 2018-09 updates a variety of topics in order to clarify, correct errors, or make minor improvements to the Codification, making it easier to understand and easier to apply by eliminating inconsistencies and providing clarifications. Certain amendments in ASU 2018-09 were effective upon issuance, others are effective for annual periods beginning after December 15, 2018 for public business entities, and some have been made to recently issued guidance and will be subject to the effective dates within the relevant guidance. The adoption of ASU 2018-09 did not have a significant impact on our consolidated financial statements.

r. Recently Issued Accounting Standards: In August 2018, the FASB issued ASU No. 2018-13,*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement.* ASU 2018-13 is intended to improve the effectiveness of disclosure requirements on fair value measurements in Topic 820. ASU 2018-13 modifies certain disclosure requirements and will be effective for annual and interim reporting periods beginning after December 15, 2019. We do not expect the adoption of ASU 2018-13 to have any impact on our consolidated financial statements, however it may have an impact on our fair value disclosures.

In December 2019, the FASB issued ASU No. 2019-12,*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* ASU 2019-12 is intended to improve consistent application and simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance. ASU 2019-12 is effective for annual and interim reporting periods beginning after December 12, 2020, with early adoption permitted. We do not expect the adoption of ASU 2019-12 to have a material impact on our consolidated financial statements.

2. Liquidity

The Company has been engaged in litigation with Platinum-Montaur Life Sciences LLC ("Platinum-Montaur"), an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P., Platinum Partners Capital Opportunity Fund, Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, "Platinum"), in which Platinum-Montaur was seeking damages of approximately $1.9 million plus interest. See Notes 12 and 14.

In addition, the Company is engaged in ongoing litigation with our former President and Chief Executive Officer, Dr. Michael Goldberg. See Notes 10 and 14.

The Company has also been engaged in ongoing litigation with Capital Royalty Partners II L.P. ("CRG") and pursuing recovery of approximately $4.3 million and other damages. On November 27, 2019, the Court of Common Pleas of Franklin County, Ohio (the "Ohio Court") entered a judgment in the amount of $4.3 million to Navidea, plus statutory interest from April 9, 2018 (the "Judgment"). See Notes 12 and 14.

In February 2020, the Company executed a binding term sheet to sell the Judgment for $4.2 million of proceeds to Navidea. The Company has the option, within 45 days of the sale, to repurchase the Judgment for a 10% premium. Such repurchase option may be in the form of the Company's Common Stock at a 10% discount to the then-current market price.

In June 2019, the Company completed an underwritten public offering of 8,000,000 shares (the "Shares") of our Common Stock pursuant to the Underwriting Agreement at a price to the public of $0.75 per share. Of the 8,000,000 total Shares, 4,000,000 shares were placed with existing investor John K. Scott, Jr. at a price of $0.75 per share. Pursuant to the Underwriting Agreement, the Underwriter purchased the remaining 4,000,000 Shares from the Company at a price of $0.69375 per share. After underwriting discounts, commissions, fees and expenses paid to the Underwriter, the Company received net proceeds from the offering of $5,555,000.

In December 2019, the Company executed a Stock Purchase Agreement with the investors named therein. Pursuant to the Stock Purchase Agreement, the investors agreed to purchase approximately 2.1 million shares of the Company's Common Stock in a private placement for aggregate gross proceeds to the Company of approximately $1.9 million. Of this amount, approximately $1.1 million was received during 2019, resulting in approximately $812,000 of stock subscriptions receivable as of December 31, 2019. The remaining $812,000 of proceeds were received and the related Common Stock was issued in January 2020.

In February 2020, the Company executed agreements with two existing investors to purchase approximately 4.0 million shares of the Company's Common Stock for aggregate gross proceeds to Navidea of approximately $3.4 million.

Navidea intends to use the net proceeds from these transactions to fund its research and development programs, including continued advancement of its two Phase 2b and Phase 3 clinical trials of Tc99m tilmanocept in patients with rheumatoid arthritis, and for general working capital purposes and other operating expenses. See Notes 15 and 21.

The Company has experienced recurring net losses and has used significant cash to fund its operations. The Company has considerable discretion over the extent of development project expenditures and has the ability to curtail the related cash flows as needed. The December 2019 and February 2020 transactions described above provided approximately $9.5 million of additional working capital. 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 filing of this Annual Report on Form 10-K.

3. Discontinued Operations

In March 2017, Navidea completed the Asset Sale to Cardinal Health 414. On April 2, 2018, the Company entered into an Amendment to the Purchase Agreement (the "Amendment"). 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 in favor of CRG (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. On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit.

4. Revenue from Contracts with Customers

Navidea is focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. 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 (ii) therapeutic development programs, including all therapeutic applications of our Manocept platform. Tc99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, is the only one of the Company's drug product candidates that has been approved for sale in any market. The Company has license and distribution agreements in place in Europe, India and China, however Tc99 tilmanocept has only been approved for sale in Europe.

The Company also has an agreement in place to provide Meilleur Technologies, Inc. ("Meilleur"), a wholly-owned subsidiary of Cerveau Technologies, Inc., 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.

The Company adopted ASU 2014-09, along with all subsequent related ASUs impacting revenue from contracts with customers (collectively, "the new revenue recognition standard"), effective January 1, 2018, using the modified retrospective method of adoption. The Company has applied the new revenue recognition standard with the cumulative effect of initially applying the new accounting recognized on January 1, 2018 as an adjustment to opening accumulated deficit. This adjustment reflects only contracts that were not completed as of January 1, 2018.

The cumulative effect of the change on accumulated deficit as of January 1, 2018 was an increase of $700,000, consisting of $100,000 related to an up-front payment received upon execution of an exclusive license and distribution agreement with Sayre Therapeutics for the development and commercialization of Tc99m tilmanocept in India in June 2017, and $600,000 related to up-front and milestone payments received pursuant to an exclusive licensing and distribution agreement with Beijing Sinotau Medical Research Co., Ltd. for the marketing and distribution of Tc99m tilmanocept in China executed in August 2014. The following table compares deferred revenue as if the new revenue recognition standard had not been adopted to the amounts in the consolidated financial statements reflecting the adoption. Deferred revenue, the current portion of which is included in accrued liabilities and other in the consolidated balance sheets, and accumulated deficit are the only financial statement line items that were affected by the adoption of the new revenue recognition standard.

	Pre-Adoption	Post-Adoption	Change
Deferred revenue	$ 26,061	$ 726,061	$ 700,000
Accumulated deficit	(319,908,968)	(320,608,968)	(700,000)

Currently, the Company recognizes revenue from up-front license fees and pre-market milestones after the cash has been received from its customers and the performance obligations have been met. Payments for sales-based royalties and milestones are generally received after the related revenue has been recognized and invoiced. Normal payment terms generally range from 15 to 90 days following milestone achievement or royalty invoice, in accordance with each contract.

Up-front and milestone payments received related to our license and distribution agreements in India and China are deferred until Tc99m tilmanocept has been approved by the regulatory authorities in each of those countries. It is not possible to determine with any degree of certainty whether or when regulatory approval for this product will be achieved in India or China, if at all. In addition, since sales of Tc99m tilmanocept have not yet begun in India or China, there is no basis for estimating whether, to what degree, or the rate at which the product will be accepted and utilized in these markets. Therefore, it is not possible to determine with any degree of certainty the expected sales in future periods in those countries. As such, the Company intends to recognize revenue from up-front and milestone payments on a straight-line basis beginning at the time of regulatory approval in each country through the end of the initial term of each agreement. The initial term of each agreement is eight years in India and 10 years in China.

The transaction price of a contract is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. Transaction prices do not include amounts collected on behalf of third parties (e.g., sales taxes). To determine the transaction price of a contract, the Company considers the terms of the contract. For the purpose of determining transaction prices, the Company assumes that the goods or services will be transferred to the customer as promised in accordance with existing contracts and that the contracts will not be cancelled, renewed, or modified.

When estimating a contract's transaction price, the Company considers all the information (historical, current, and forecasted) that is reasonably available to it and identifies possible consideration amounts. Most of the Company's contracts with customers include both fixed and variable components of the transaction price. Under those contracts, some or all of the consideration for satisfied performance obligations is contingent on events over which the Company has no direct influence. For example, regulatory approval or product sales volume milestones are contingent upon the achievement of those milestones by the distributor. Additionally, the prices charged to end users of Tc99m tilmanocept, upon which royalty payments are based in Europe, India and China, are set by the distributor in each of those countries.

The milestone payments have a binary outcome (that is, the Company will either receive all or none of each milestone payment) and can be estimated using the most-likely-amount method. Taking into account the constraint on variable consideration, the Company has assessed the likelihood of achieving the non-sales-based milestone payments in our contracts and has determined that it is probable the milestones will be achieved and the Company will receive the consideration. Accordingly, it is probable that including those payments in the transaction price will not result in a significant revenue reversal when the contingency is resolved. Therefore, the amount of the non-sales-based milestone payments is included in the transaction price.

Royalties are estimated based on the expected value method because they are based on a variable amount of sales representing a range of possible outcomes. However, when taking into account the constraint on variable consideration, the estimate of future royalties included in the transaction price is generally $0. This conclusion is based on the fact that Tc99m tilmanocept is early in the commercial launch process in Europe and sales have not yet begun in India or China, therefore there is currently no basis for estimating whether, to what degree, or the rate at which the product will be accepted and utilized in these markets. Similarly, we currently have no basis for estimating whether sales-based milestones will ever be achieved. Accordingly, the Company recognizes revenue from royalties when the related sales occur and from sales-based milestones when they are achieved.

The sublicense of NAV4694 to Meilleur provides for payments to Navidea including up-front payments, milestones, an option for worldwide commercial rights, royalties on net sales, and reimbursement for product development assistance during the initial transition period. In accordance with the revenue recognition standard, the upfront payments were recognized upon contract inception, and reimbursement for product development assistance will be recognized on a monthly basis. Should some or all of the variable consideration from milestones, the option and royalties meet the requirements of the revenue recognition standard to be included in the transaction price, those amounts will be recognized as revenue in future periods.

Up-front fees, milestones and royalties are generally non-refundable. Therefore, the Company does not estimate expected refunds nor do we adjust revenue downward. The Company will evaluate and update the estimated transaction prices of its contracts with customers at the end of each reporting period.

During the years ended December 31, 2019 and 2018, the Company recognized revenue from contracts with customers of approximately $38,000 and $338,000, respectively. During the years ended December 31, 2019 and 2018, the Company did not recognize any related impairment losses, nor did the Company recognize any revenue from performance obligations associated with long-term contracts that were satisfied (or partially satisfied) in previous periods.

The following tables disaggregate the Company's revenue from contracts with customers for the years ended December 31, 2019 and 2018.

Year Ended December 31, 2019	**Diagnostics**
Royalty revenue:	
Europe	$ 16,665
License revenue:	
NAV4694 sublicense	$ 9,953
Other revenue:	
Additional stability studies	$ 11,024

Year Ended December 31, 2018	**Diagnostics**
Royalty revenue:	
Europe	$ 15,347
License revenue:	
NAV4694 sublicense	$ 287,569
Tc99m tilmanocept sublicense, China	19,605
Total	$ 307,174
Other revenue:	
Additional stability studies	$ 15,037

The following economic factors affect the nature, amount, timing and uncertainty of the Company's revenue and cash flows as indicated:

Geographical Location of Customers: Drug pricing models vary among different markets, which in turn may affect the royalty rates and milestones we are able to negotiate with our distributors in those markets. Royalty rates and milestone payments vary by contract but may be based in part on the potential market size in each territory. In the case of Tc99m tilmanocept, royalty rates for Europe are lower than rates in India but higher than in China.

Status of Regulatory Approval: The majority of revenue from contracts with customers will generally be recognized after the product is approved for sale in each market. Each Tc99m tilmanocept customer operates in its own distinct regulatory environment, and the laws and pathways to drug product approval vary by market. Tc99m tilmanocept has been approved for sale in Europe, thus the Company has begun to recognize royalties from sales in Europe. Tc99m tilmanocept has not yet been approved for sale in India or China, and may never achieve approval in those markets. The regulatory pathways and timelines in those markets will impact whether and when the Company recognizes the related royalties and milestones. Similarly, NAV4694 has not yet been approved for sale in any market, thus the timing of any revenue related to that product will be dependent on the regulatory pathways and timelines in each market in which Meilleur seeks regulatory approval.

Through December 31, 2019, the Company has not capitalized any contract-related costs as contract assets.

The following table summarizes the changes in contract liabilities, the current portion of which is included in accrued liabilities and other in the consolidated balance sheets, during the years ended December 31, 2019 and 2018.

	Year Ended December 31,	
	2019	2018
Total deferred revenue, beginning of period	$ 711,024	$ 26,061
Impact of adoption of ASU 2014-09 and related standards	—	700,000
Revenue deferred related to sublicense	495,000	10,000
Refund of deferred revenue related to sublicense	(495,000)	—
Revenue recognized from satisfaction of performance obligations	(11,024)	(25,037)
Total deferred revenue, end of period	$ 700,000	$ 711,024

The Company had trade receivables of approximately $0 and $12,000 outstanding as of December 31, 2019 and 2018, respectively.

In addition to revenue from contracts from customers, we also generate revenue from National Institutes of Health ("NIH") grants to support various product development initiatives. The revenue recognition standard applies to revenue from contracts with customers. A customer is defined as a party that has contracted with an entity to obtain goods or services that are an output of the entity's ongoing major or central operations in exchange for consideration. The Company's ongoing major or central operations consist of the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. The NIH and its various institutes are responsible for biomedical and public health research and provide major biomedical research funding to non-NIH research facilities and entities such as Navidea. While the Company will directly benefit from any knowledge gained from the project, there is also a public health benefit provided, which justifies the use of public funds in the form of the grants. Based on the nature of the Company's operations and the terms of the grant awards, Navidea does not have a vendor-customer relationship with the NIH and the grant awards are outside the scope of the revenue recognition standard. Accordingly, the revenue recognition standard need not be applied to the NIH grants. During the years ended December 31, 2019 and 2018, the Company recognized grant revenue of $611,000 and $761,000, respectively.

5. Fair Value

The Company's available-for-sale securities consist of certificates of deposit which are measured using Level 2 inputs.

MT issued warrants to purchase MT common stock with certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value on the consolidated balance sheets. The estimated fair value of the MT warrants, which is measured using Level 3 inputs, is $0 and $63,000 at December 31, 2019 and 2018, respectively, and is included in other liabilities on the accompanying consolidated balance sheets, and will continue to be measured on a recurring basis until the MT warrants expire in March 2020. See Notes 1(m) and 10.

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

Assets and Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2018

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Certificates of deposit	$ —	$ 799,270	$ —	$ 799,270
Liabilities:				
Liability related to MT warrants	$ —	$ —	$ 63,000	$ 63,000

a. Valuation Processes-Level 3 Measurements: The Company utilizes third-party valuation services that use complex models such as Monte Carlo simulation to estimate the value of our financial liabilities.

b. Sensitivity Analysis-Level 3 Measurements: Changes in the valuation of MT as a whole may cause material changes in the fair value of the MT warrants. Significant increases (decreases) in the valuation of MT, such as may be the result of additional financing, could result in a higher (lower) fair value measurement. A change in the valuation of MT would not necessarily result in a directionally similar change in the value of the MT warrants.

There were no transfers in or out of our Level 1 or Level 2 liabilities during the years ended December 31, 2019 and 2018. Changes in the estimated fair value of our Level 3 liabilities relating to unrealized gains (losses) are recorded as changes in fair value of financial instruments in the consolidated statements of operations.

6. Stock-Based Compensation

For the years ended December 31, 2019 and 2018, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $232,000 and $307,000, respectively. We have not recorded any income tax benefit related to stock-based compensation for the years ended December 31, 2019 and 2018.

A summary of the status of our stock options as of December 31, 2019, and changes during the year then ended, is presented below:

	Year Ended December 31, 2019			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2019	157,915	$ 24.82		
Granted	95,250	5.89		
Canceled and forfeited	(5,304)	8.94		
Expired	(9,391)	30.87		
Outstanding, December 31, 2019	238,470	$ 17.38	7.2	$ —
Exercisable, December 31, 2019	84,807	$ 31.77	5.0	$ —

The weighted average grant-date fair value of options granted in 2019 and 2018 was $1.65 and $4.00, respectively. No stock options were exercised during 2019 or 2018. The aggregate fair value of stock options vested during 2019 and 2018 was $0 in both years.

A summary of the status of our unvested restricted stock as of December 31, 2019, and changes during the year then ended, is presented below:

	Year Ended December 31, 2019	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested, January 1, 2019	5,000	$ 7.42
Granted	15,000	2.75
Vested	(5,000)	7.42
Unvested, December 31, 2019	15,000	$ 2.75

During 2019 and 2018, 5,000 and 10,000 shares, respectively, of restricted stock vested with aggregate vesting date fair values of $14,000 and $59,000, respectively.

In March 2018, 5,000 shares of restricted stock held by a non-employee director with an aggregate fair value of $36,000 vested upon his retirement from the Board. In August 2018, 2,500 shares of restricted stock held by a non-employee director with an aggregate fair value of $7,000 were forfeited as a result of his departure from the Board. During 2019 and 2018, 5,000 and 5,000 shares of restricted stock held by non-employee directors with aggregate fair values of $14,000 and $23,000, respectively, vested as scheduled according to the terms of the restricted stock agreements.

As of December 31, 2019, there was approximately $46,000 of total unrecognized compensation cost related to stock option and restricted stock awards, which we expect to recognize over remaining weighted average vesting terms of 1.0 years. See Note 1(e).

7. Loss Per Share

Basic loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares. Diluted loss per share reflects additional common shares that would have been outstanding if dilutive potential common shares had been issued. Potential common shares that may be issued by the Company include convertible debt, convertible preferred stock, options and warrants.

Diluted loss per common share for the years ended December 31, 2019 and 2018 excludes the effects of 1,487,681 and 892,983 common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of common shares issuable upon exercise of outstanding stock options and warrants.

The Company's unvested stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as "participating securities"). Therefore, the unvested stock awards are required to be included in the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, 15,000 and 5,000 shares of unvested restricted stock for the years ended December 31, 2019 and 2018, respectively, were excluded in determining basic and diluted loss per share because such inclusion would be anti-dilutive.

8. Accounts and Other Receivables and Concentrations of Credit Risk

Accounts and other receivables at December 31, 2019 and 2018 consist of the following:

	2019	2018
Stock subscriptions	$ 811,946	$ —
Grant revenue	84,366	3,905
Trade	—	12,378
Other	5,027	4,868
Total accounts and other receivables	$ 901,339	$ 21,151

At December 31, 2019, approximately 90% of net accounts and other receivables were due from an investor. At December 31, 2018, approximately 47% of net accounts and other receivables were due from Meilleur. As of December 31, 2019 and 2018, there was no allowance for doubtful accounts. We do not believe we are exposed to significant credit risk related to the receivable due from the investor based on the timely payment history of the entity. We believe that we have adequately addressed credit risks in estimating the allowance for doubtful accounts. See Note 1(h).

9. Property and Equipment

The major classes of property and equipment are as follows:

	Useful Life (in years)	2019	2018
Production machinery and equipment	5	$ 575,091	$ 575,091
Other machinery and equipment, primarily computers and research equipment	3 – 5	296,987	323,259
Furniture and fixtures	7	2,576	4,327
Purchased software	3	320,435	336,060
Leasehold improvements*	Term of Lease	12,448	12,448
Total property and equipment		$ 1,207,537	$ 1,251,185

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

During 2019 and 2018, we recorded $103,000 and $121,000, respectively, of depreciation and amortization related to property and equipment. See Note 1(i).

10. Investment in Macrophage Therapeutics, Inc.

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

The warrants have certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value, with subsequent changes in fair value included in earnings. The fair value of the warrants was estimated to be $63,000 at issuance. At December 31, 2019, the fair value of the warrants was determined to be $0 due to their March 2020 expiration date and MT's insolvency. See Notes 1(m) and 5. In addition, certain provisions of the Securities Purchase Agreement obligate the MT Investors to acquire the remaining MT Preferred Stock and related warrants for $2.0 million at the option of MT. The estimated relative fair value of this put option was $113,000 at issuance based on the Black-Scholes option pricing model and is classified within stockholders' equity.

In addition, we entered into a Securities Exchange Agreement with the MT Investors providing them an option to exchange their MT Preferred Stock for our Common Stock in the event that MT has not completed a public offering with gross proceeds to MT of at least $50 million by the second anniversary of the closing of the initial sale of MT Preferred Stock, at an exchange rate per share obtained by dividing $50,000 by the greater of (i) 80% of the twenty-day volume weighted average price per share of our Common Stock on the second anniversary of the initial closing or (ii) $60.00. To the extent that the MT Investors do not timely exercise their exchange right, MT has the right to redeem their MT Preferred Stock for a price equal to $58,320 per share. We also granted MT an exclusive sublicense for certain therapeutic applications of the Manocept technology.

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

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

Goldberg Litigation

In August 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 an Agreement (the "Goldberg Agreement"), with the intent of entering into one or more additional Definitive Agreements, which set forth the terms of the separation from service. Among other things, the Goldberg Agreement provided that Dr. Goldberg would be entitled to 1,175,000 shares of our Common Stock, representing in part payment of accrued bonuses and payment of the balance of the Platinum debt. A portion of the 1,175,000 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 debt to a party other than Dr. Goldberg. Further, the Goldberg Agreement provided that the Company's subsidiary, MT, would 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. In November 2018, the Company issued 925,000 shares of our Common Stock to Dr. Goldberg, 250,000 of which were placed in escrow in accordance with the Goldberg Agreement.

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 in accordance with its terms, effective March 1, 2019, due to MT's insolvency. On February 20, 2019, the MT Board 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 Jed A. Latkin to serve as President and Chief Executive Officer of MT.

New York Litigation Involving Dr. Goldberg

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the United States District Court, Southern District of New York (the "District Court"), alleging breach of the Goldberg 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 Goldberg Agreement is excused and that Navidea is entitled to terminate the Goldberg Agreement as a result of Dr. Goldberg's actions. On April 26, 2019, Navidea filed an amended complaint against Dr. Goldberg which added a claim for breach of fiduciary duty seeking damages related to certain actions Dr. Goldberg took while CEO of Navidea. On June 13, 2019, Dr. Goldberg answered the amended complaint and asserted counterclaims against Navidea and third-party claims against MT for breach of the Goldberg Agreement, wrongful termination, injunctive relief, and quantum meruit.

On December 26, 2019, the District Court ruled on several motions related to Navidea and MT and Dr. Goldberg that substantially limited the claims that Dr. Goldberg can pursue against Navidea and MT. Specifically, the District Court found that certain portions of Dr. Goldberg's counterclaims against Navidea and third-party claims against Macrophage failed to state a claim upon which relief can be granted. Specifically, the District Court ruled that actions taken by Navidea and MT, including reconstituting the MT Board, replacing Dr. Goldberg with Mr. Latkin as Chief Executive Officer of MT, terminating the sublicense between Navidea and MT, terminating certain research projects, and allowing MT intellectual property to revert back to Navidea, were not breaches of the Goldberg Agreement.

The District Court also rejected Dr. Goldberg's claim for wrongful termination as Chief Executive Officer of MT. In addition, the District Court found that Dr. Goldberg lacked standing to seek injunctive relief to force the removal of Dr. Claudine Bruck and Michael Rice from MT's Board of Directors, to invalidate all actions taken by the MT Board on or after November 29, 2018 (the date upon which Dr. Bruck and Mr. Rice were appointed by Navidea to the Board of MT), or to reinstate the terminated sublicense between Navidea and MT.

In addition, the District Court found Navidea's breach of fiduciary duty claim against Dr. Goldberg for conduct occurring more than three years prior to the filing of the complaint to be time-barred and that Dr. Goldberg is entitled to an advancement of attorneys' fees solely with respect to that claim. The parties are in the process of submitting the issue to the District Court for resolution on how much in fees Dr. Goldberg is owed under the District Court's order. On January 27, 2020, Dr. Goldberg filed a motion seeking additional advancement from Navidea for fees in connection with the New York Action and the Delaware Action. Navidea has opposed the motion.

On January 31, 2020, Goldberg filed a motion for leave to amend his complaint to add back in claims for breach of contract, breach of the implied covenant of good faith and fair dealing, quantum meruit and injunctive relief. Navidea and MT have opposed the motion. The discovery deadline in the New York Action is April 15, 2020.

Delaware Litigation Involving Dr. Goldberg

On February 20, 2019, MT initiated a suit against Dr. Goldberg in the Court of Chancery of the State of Delaware (the "Delaware Court"), 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 effect are void. On June 12, 2019, the Delaware Court found that Dr. Goldberg's actions were not authorized in compliance with the Delaware General Corporate Law. Specifically, the Delaware Court found that Dr. Goldberg's creation of a new subsidiary of MT and the purported assignment by Dr. Goldberg of MT's intellectual property to that subsidiary were void. The Delaware Court's ruling follows the order on May 23, 2019 in the case, in which it found Dr. Goldberg in contempt of its prior order holding Dr. Goldberg responsible for the payment of MT's fees and costs to cure the damages caused by Dr. Goldberg's contempt. MT's claims for breach of fiduciary duty and conversion against Dr. Goldberg remain pending. As a result of the Delaware Court's ruling and Navidea's prior termination of the sublicense between itself and MT, all of the intellectual property related to the Manocept platform is now directly controlled by Navidea. A trial on MT's claims against Goldberg for breach of fiduciary duty and conversion is presently scheduled for June 2020.

Derivative Action Involving Dr. Goldberg

On July 26, 2019, Dr. Goldberg served shareholder demands on the Boards of Navidea and MT repeating many of the claims made in the lawsuits described above. On or about November 20, 2019, Dr. Goldberg commenced a derivative action purportedly on behalf of MT in the District Court against Dr. Claudine Bruck, Y. Michael Rice, and Jed Latkin alleging a claim for breach of fiduciary duty based on the actions alleged in the demands. On January 30, 2020, a pre-motion conference was conducted before the District Court on an anticipated motion to dismiss and Dr. Goldberg has agreed to dismiss the derivative action in New York without prejudice and retains the ability to re-file the action in Delaware. See Notes 2 and 14.

11. Accounts Payable, Accrued Liabilities and Other

Accounts payable at December 31, 2019 and 2018 includes an aggregate of $65,000 and $0, respectively, due to related parties for director fees. Accrued liabilities and other at December 31, 2019 and 2018 includes an aggregate of $925,000 and $1.6 million, respectively, due to related parties for accrued termination costs, bonuses and director fees.

Accrued liabilities and other at December 31, 2019 and 2018 consist of the following:

	2019	2018
Contracted services	$ 1,212,347	$ 866,934
Compensation	925,009	1,637,337
Other	13,618	12,776
Total accrued liabilities and other	$ 2,150,974	$ 2,517,047

12. Notes Payable

Platinum-Montaur Life Sciences LLC

In July 2012, we entered into an agreement with Platinum-Montaur to provide us with a credit facility of up to $50 million (the "Platinum Loan Agreement"). In November 2018, the Company issued 925,000 shares of our Common Stock to Dr. Goldberg, of which approximately 817,857 shares valued at $3.2 million were applied as final payment of the Platinum debt, including principal and accrued interest of $2.2 million and loss on extinguishment of debt of $1.0 million. During the year ended December 31, 2018, $153,000 of interest was compounded and added to the balance of the Platinum debt. See Notes 2 and 14.

Capital Royalty Partners II, L.P.

In May 2015, Navidea and MT, as guarantor, executed a Term Loan Agreement (the "CRG Loan Agreement") with CRG in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the "Lenders") in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of $50.0 million (the "CRG Term Loan"). Closing and funding of the CRG Term Loan occurred on May 15, 2015 (the "Effective Date"). The principal balance of the CRG Term Loan bore interest from the Effective Date at a per annum rate of interest equal to 14.0%. The Company initially had the option of paying (i) 10.00% of the per annum interest in cash and (ii) 4.00% of the per annum interest as compounded interest which is added to the aggregate principal amount of the CRG Term Loan. During 2015 and 2016, a total of $1.8 million of interest was compounded and added to the balance of the CRG Term Loan. In addition, the Company began paying the cash portion of the interest in arrears on June 30, 2015. Principal was due in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, was due and payable in full on March 31, 2021. Pursuant to a notice of default letter sent to Navidea by CRG in April 2016, the Company stopped compounding interest in the second quarter of 2016 and began recording accrued interest.

The CRG Term Loan was collateralized by a security interest in substantially all of the Company's assets. In addition, the CRG Loan Agreement required that the Company adhere to certain affirmative and negative covenants, including financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the CRG Loan Agreement. The Lenders could accelerate the payment terms of the CRG Loan Agreement upon the occurrence of certain events of default set forth therein. An event of default would entitle CRG to accelerate the maturity of the CRG Term Loan, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas (the "Texas Court") on April 7, 2016. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of $4.1 million that was on deposit, applying $3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining $189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414. In accordance with a Global Settlement Agreement, on March 3, 2017, the Company repaid $59.0 million of its indebtedness and other obligations outstanding under the CRG Term Loan.

Following a trial in December 2017, the Texas Court ruled that the Company's total obligation to CRG was in excess of $66.0 million, limited to $66.0 million under the Global Settlement Agreement. The Texas Court acknowledged only the $59.0 million payment made in March 2017, concluding that the Company owed CRG another $7.0 million, however the Texas Court did not expressly take the Company's June 2016 payment of $4.1 million into account and awarded, as part of the $66.0 million, amounts that had already been paid as part of the $4.1 million. In April 2018, CRG drew approximately $7.1 million on a letter of credit that was established pursuant to the Global Settlement Agreement. This was in addition to the $4.1 million and the $59.0 million that Navidea had previously paid to CRG. See Notes 2 and 14.

IPFS Corporation

In November 2017, we prepaid $396,000 of insurance premiums through the issuance of a note payable to IPFS Corporation ("IPFS") with an interest rate of 4.0%. The note was payable in ten monthly installments of $40,000, with the final payment made in August 2018. In November 2018, we prepaid $393,000 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 5.1%. The note was payable in ten monthly installments of $40,000, with the final payment made in August 2019.

Interest expense related to the IPFS notes payable totaled $6,000 and $8,000 during the years ended December 31, 2019 and 2018, respectively. The balance of the IPFS note was approximately $316,000 as of December 31, 2018, and was included in notes payable, current in the consolidated balance sheets.

First Insurance Funding

In November 2019, we prepaid $349,000 of insurance premiums through the issuance of a note payable to First Insurance Funding ("FIF") with an interest rate of 5.0%. The note is payable in eight monthly installments of $44,000, with the final payment due in July 2020.

Interest expense related to the FIF note payable totaled $1,000 during the year ended December 31, 2019. The balance of the FIF note was approximately $306,000 as of December 31, 2019, and was included in notes payable, current in the consolidated balance sheets.

Summary

During the years ended December 31, 2019 and 2018, we recorded interest expense of $8,000 and $161,000, respectively, related to our notes payable. Of those amounts, $0 and $153,000 was compounded and added to the balance of the Platinum debt during the year ended December 31, 2018.

Annual principal maturities of our notes payable are $306,000 in 2020.

13. Leases

We currently lease approximately 5,000 square feet of office space at 4995 Bradenton Avenue, Dublin, Ohio, as our principal offices, at a monthly base rent of approximately $3,000. The current lease term expires in June 2020 with an option to extend for an additional three years. In March 2020, we executed an amendment to extend the lease term through June 2023 at a monthly base rent of approximately $3,000.

We also leased approximately 2,000 square feet of office space at 560 Sylvan Avenue, Englewood Cliffs, New Jersey, at a monthly base rent of approximately $3,000. The lease for the New Jersey office space expired on March 31, 2019 and we did not renew.

In addition, we currently lease approximately 25,000 square feet of office space at 5600 Blazer Parkway, Dublin, Ohio, formerly our principal offices, at a monthly base rent of approximately $26,000 during 2019. The current lease term expires in October 2022 with an option to extend for an additional five years. The Company does not intend to renew this lease. 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.

We also currently lease a vehicle at a monthly payment of approximately $300, expiring in September 2021, and office equipment at a monthly payment of approximately $100, expiring in October 2024.

We adopted ASU 2016-02, *Leases (Topic 842)* effective January 1, 2019. The following table summarizes the impact of the adoption of ASU 2016-02 on our balance sheet at January 1, 2019.

	Operating Lease Right-of-Use Assets	Operating Lease Liabilities	Terminated Lease Liability	Deferred Rent
Pre-adoption balance	$ —	$ —	$ 589,173	$ 2,587
Change	406,842	998,602	(589,173)	(2,587)
Post-adoption balance	$ 406,842	$ 998,602	$ —	$ —

Total operating lease expense was $229,000 for the year ended December 31, 2019. Sublease income was $378,000 for the year ended December 31, 2019, and was recorded in selling, general and administrative expenses. Prior to the implementation of ASU 2016-02, total rental expense related to our operating leases was $68,000 for the year ended December 31, 2018.

The following table presents information about the amount, timing and uncertainty of cash flows arising from the Company's operating leases as of December 31, 2019.

Maturity of Lease Liabilities	Operating Lease Payments
2020	$ 320,662
2021	308,407
2022	254,966
2023	1,626
2024	1,355
Total undiscounted operating lease payments	887,016
Less imputed interest	124,119
Present value of operating lease liabilities	$ 762,897
Balance Sheet Classification	
Current lease liabilities	$ 250,553
Noncurrent lease liabilities	512,344
Total operating lease liabilities	$ 762,897
Other Information	
Weighted-average remaining lease term for operating leases (in years)	2.7
Weighted-average discount rate for operating leases	10.9%

An initial right-of-use lease asset of $407,000 was recognized as a non-cash asset addition with the adoption of ASU 2016-02. The discount rates used for each lease were based principally on the Platinum debt, which was secured and outstanding for most of 2018. A "build-up" method was utilized where the approach was to estimate the risk/credit spread priced into the debt rate and then adjust that for the remaining term of each lease. Additionally, some market research was completed on the Company's peer group as identified for purposes of compensation analysis. Cash paid for amounts included in the present value of operating lease liabilities was $330,000 during the year ended December 31, 2019 and is included in operating cash flows.

14. Commitments and Contingencies

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

CRG Litigation

The Company has been engaged in ongoing litigation with CRG Lenders party to the CRG Loan Agreement, in the District Court of Harris County, Texas relating to CRG's claims of default under the terms the CRG Loan Agreement. Following a trial in December 2017, the Texas Court ruled that the Company's total obligation to CRG was in excess of $66.0 million, limited to $66.0 million under the Global Settlement Agreement. The Texas Court acknowledged only the $59.0 million payment made in March 2017, concluding that the Company owed CRG another $7.0 million, however the Texas Court did not expressly take the Company's June 2016 payment of $4.1 million into account and awarded, as part of the $66.0 million, amounts that had already been paid as part of the $4.1 million. The Company believes that this $4.1 million should be credited against the $7.0 million and has appealed the Texas Court's judgment. The Court of Appeals dismissed the Company's appeal without reaching the merits due to a contractual waiver of appeal.

On April 9, 2018, CRG drew approximately $7.1 million on the Cardinal Health 414 letter of credit. These were funds to which Navidea would otherwise have been entitled. This was in addition to the $4.1 million and the $59.0 million that Navidea had previously paid to CRG.

The Company has also been engaged in ongoing litigation with CRG in the Court of Common Pleas of Franklin County, Ohio related to Navidea's claims that the Lenders fraudulently induced Navidea to enter into a settlement agreement and breached the terms of the same through certain actions taken by the Lenders in connection with the Global Settlement Agreement reached in 2017, pursuant to which Navidea agreed to pay up to $66.0 million to Lenders, as well as through actions and misrepresentations by CRG after the Global Settlement Agreement was executed. The claims in that suit are for breach of contract, conversion and unjust enrichment against the Lenders for their collection of more than $66.0 million, the maximum permitted under the Global Settlement Agreement, and their double recovery of amounts paid as part of the $4.1 million paid in June 2016 and recovered again as part of the $66.0 million. CRG's double recovery and recovery of more than $66.0 million are due to CRG drawing the entire $7.1 million on the Cardinal Health 414 letter of credit. The Lenders sought a Writ of Prohibition in the Ohio Supreme Court to prevent this case from moving forward, which was denied, and proceedings resumed in front of the Ohio Court. Following an unsuccessful mediation on May 7, 2019, Navidea moved for Summary Judgment on June 28, 2019. On November 27, 2019, the Ohio Court found that when CRG collected more than $66.0 million, they took an excess recovery and breached the Global Settlement Agreement. The Ohio Court awarded approximately $4.3 million to Navidea, plus statutory interest from April 9, 2018, the date CRG drew on the Cardinal Health 414 letter of credit. The Ohio Court also found that there was no unjust enrichment or conversion by CRG since this was a matter of contract and only contract damages were appropriate. The decision is a final appealable order and terminates the case. On December 5, 2019, CRG filed a notice of appeal with Ohio's 10th District Court of Appeals regarding the judgment in favor of Navidea. The parties are currently in the process of briefing the appeal. The briefing of the appeal is expected to conclude on March 27, 2020. Oral argument may be held on the appeal after the briefing is filed.

CRG filed another lawsuit in the Texas Court in April 2018. This suit seeks a declaratory judgment that CRG did not breach the Global Settlement Agreement by drawing the entire $7.1 million on the Cardinal Health 414 letter of Credit. CRG also alleges that the Company breached the Global Settlement Agreement by appealing the Texas Court's judgment and by filing the suit in Franklin County, Ohio. The Company moved to dismiss CRG's claims under the Texas Citizens' Participation Act. The Texas Court denied the motion to dismiss. The Company filed an interlocutory appeal of the denial of its motion to dismiss. That appeal is fully briefed, and the parties await the court of appeals' ruling. Proceedings in the Texas Court are stayed pending resolution of that appeal. See Notes 2 and 12.

Platinum Litigation

In November 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York (the "New York Supreme Court"), 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 subsequently removed to the United States District Court for the Southern District of New York (the "District Court"). 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. The Second Circuit held oral argument in this matter on September 5, 2019. On November 25, 2019, the Second Circuit issued a decision which remanded the case to the District Court for further consideration of whether the District Court had jurisdiction over the case following removal from the New York Supreme Court. The Second Circuit did not address the merits of Platinum-Montaur's allegations against Navidea. By agreement of the parties, the case has now been remanded from the District Court to the New York Supreme Court. A preliminary conference is set for April 28, 2020. See Notes 2 and 12.

Goldberg Agreement and Litigation

In August 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 Goldberg Agreement, with the intent of entering into one or more additional Definitive Agreements, which set forth the terms of the separation from service. Among other things, the Goldberg Agreement provided that Dr. Goldberg would be entitled to 1,175,000 shares of our Common Stock, representing in part payment of accrued bonuses and payment of the balance of the Platinum debt. A portion of the 1,175,000 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 debt to a party other than Dr. Goldberg. Further, the Goldberg Agreement provided that the Company's subsidiary, MT, would 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. In November 2018, the Company issued 925,000 shares of our Common Stock to Dr. Goldberg, 250,000 of which were placed in escrow in accordance with the Goldberg Agreement.

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 in accordance with its terms, effective March 1, 2019, due to MT's insolvency. On February 20, 2019, the MT Board 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 Jed A. Latkin to serve as President and Chief Executive Officer of MT.

New York Litigation Involving Dr. Goldberg

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the United States District Court, Southern District of New York, alleging breach of the Goldberg 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 Goldberg Agreement is excused and that Navidea is entitled to terminate the Goldberg Agreement as a result of Dr. Goldberg's actions. On April 26, 2019, Navidea filed an amended complaint against Dr. Goldberg which added a claim for breach of fiduciary duty seeking damages related to certain actions Dr. Goldberg took while CEO of Navidea. On June 13, 2019, Dr. Goldberg answered the amended complaint and asserted counterclaims against Navidea and third-party claims against MT for breach of the Goldberg Agreement, wrongful termination, injunctive relief, and quantum meruit.

On December 26, 2019, the District Court ruled on several motions related to Navidea and MT and Dr. Goldberg that substantially limited the claims that Dr. Goldberg can pursue against Navidea and MT. Specifically, the District Court found that certain portions of Dr. Goldberg's counterclaims against Navidea and third-party claims against Macrophage failed to state a claim upon which relief can be granted. Specifically, the District Court ruled that actions taken by Navidea and MT, including reconstituting the MT Board, replacing Dr. Goldberg with Mr. Latkin as Chief Executive Officer of MT, terminating the sublicense between Navidea and MT, terminating certain research projects, and allowing MT intellectual property to revert back to Navidea, were not breaches of the Goldberg Agreement.

The District Court also rejected Dr. Goldberg's claim for wrongful termination as Chief Executive Officer of MT. In addition, the District Court found that Dr. Goldberg lacked standing to seek injunctive relief to force the removal of Dr. Claudine Bruck and Michael Rice from MT's Board of Directors, to invalidate all actions taken by the MT Board on or after November 29, 2018 (the date upon which Dr. Bruck and Mr. Rice were appointed by Navidea to the Board of MT), or to reinstate the terminated sublicense between Navidea and MT.

In addition, the District Court found Navidea's breach of fiduciary duty claim against Dr. Goldberg for conduct occurring more than three years prior to the filing of the complaint to be time-barred and that Dr. Goldberg is entitled to an advancement of attorneys' fees solely with respect to that claim. The parties are in the process of submitting the issue to the District Court for resolution on how much in fees Dr. Goldberg is owed under the District Court's order. On January 27, 2020, Dr. Goldberg filed a motion seeking additional advancement from Navidea for fees in connection with the New York Action and the Delaware Action. Navidea has opposed the motion.

On January 31, 2020, Goldberg filed a motion for leave to amend his complaint to add back in claims for breach of contract, breach of the implied covenant of good faith and fair dealing, quantum meruit and injunctive relief. Navidea and MT have opposed the motion. The discovery deadline in the New York Action is April 15, 2020.

Delaware Litigation Involving Dr. Goldberg

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 effect are void. On June 12, 2019, the Delaware Court found that Dr. Goldberg's actions were not authorized in compliance with the Delaware General Corporate Law. Specifically, the Delaware Court found that Dr. Goldberg's creation of a new subsidiary of MT and the purported assignment by Dr. Goldberg of MT's intellectual property to that subsidiary were void. The Delaware Court's ruling follows the order on May 23, 2019 in the case, in which it found Dr. Goldberg in contempt of its prior order holding Dr. Goldberg responsible for the payment of MT's fees and costs to cure the damages caused by Dr. Goldberg's contempt. MT's claims for breach of fiduciary duty and conversion against Dr. Goldberg remain pending. As a result of the Delaware Court's ruling and Navidea's prior termination of the sublicense between itself and MT, all of the intellectual property related to the Manocept platform is now directly controlled by Navidea. A trial on MT's claims against Goldberg for breach of fiduciary duty and conversion is presently scheduled for June 2020.

Derivative Action Involving Dr. Goldberg

On July 26, 2019, Dr. Goldberg served shareholder demands on the Boards of Navidea and MT repeating many of the claims made in the lawsuits described above. On or about November 20, 2019, Dr. Goldberg commenced a derivative action purportedly on behalf of MT in the District Court against Dr. Claudine Bruck, Y. Michael Rice, and Jed Latkin alleging a claim for breach of fiduciary duty based on the actions alleged in the demands. On January 30, 2020, a pre-motion conference was conducted before the District Court on an anticipated motion to dismiss and Dr. Goldberg has agreed to dismiss the derivative action in New York without prejudice and retains the ability to re-file the action in Delaware. See Notes 2 and 10.

NYSE American Continued Listing Standards

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, Navidea was not in compliance with Sections 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide (the "Guide"), the highest of such standards requiring 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. In addition, the Deficiency Letter stated that the NYSE American staff (the "Staff") determined that the Company's securities had been selling for a low price per share for a substantial period of time and, pursuant to Section 1003(f)(v) of the Guide, Navidea's continued listing was predicated on it effecting a reverse stock split of our Common Stock or otherwise demonstrating sustained price improvement within a reasonable period of time.

Navidea was required to submit a plan to the NYSE American advising of actions it had taken or would take to regain compliance with the continued listing standards by February 14, 2020. On October 25, 2018, the Company received an Acceptance Letter from the NYSE American stating that the Company's plan to regain compliance was accepted. The Acceptance Letter required the Company to provide quarterly updates to the Staff concurrent with its interim/annual SEC filings. Navidea was advised by the Staff that if we failed to regain compliance with the stockholders' equity standards by February 14, 2020, the NYSE American would commence delisting procedures.

On April 2, 2019, the Company received a notification from the NYSE American requiring the Company to regain compliance with the price standard in order to be considered for continued trading through its equity plan period end date of February 14, 2020, subject to periodic review of progress consistent with the equity plan. Accordingly, the Company effected a one-for-twenty reverse split of its issued and outstanding Common Stock on April 26, 2019. On April 30, 2019, the Company received a Price Compliance Letter from the NYSE American that the reverse stock split successfully brought the Company back in compliance with the continued listing standards with respect to low selling price as described in Section 1003(f)(v).

On February 14, 2020, the Company announced the execution of several funding transactions resulting in pro forma stockholders' equity of $6.0 million, which is the amount required to comply with Sections 1003(a)(i), (ii) and (iii) of the Guide. As a result, Navidea regained compliance with Sections 1003(a)(i), (ii) and (iii) of the Guide as of the end of the plan period.

15. Equity Instruments

a. Common Stock Issued: In March 2019, the Company entered into a Stock Purchase Agreement with an existing investor, John K. Scott, Jr. (the "Investor"), pursuant to which the Company was to issue to the Investor in a private placement (the "Private Placement") up to $3.0 million in shares of Common Stock. The Private Placement was to occur in multiple tranches. The initial closing occurred on March 22, 2019, at which the Investor purchased $50,000 worth of Common Stock at a price of $2.80 per share, which was the closing price of a share of Common Stock reported on the NYSE American market for the business day immediately before the initial closing date. The remainder of the Common Stock was to be purchased by the Investor from time to time, on such date or dates to be determined by the Company and the Investor, which date was not to be later than June 15, 2019. No additional shares were purchased by the Investor prior to the June 15, 2019 expiration of the Stock Purchase Agreement, however he did participate in the June 2019 underwritten public offering

In December 2019, the Company executed a Stock Purchase Agreement with the investors named therein. Pursuant to the Stock Purchase Agreement, the investors agreed to purchase approximately 2.1 million shares of the Company's Common Stock in a private placement for aggregate gross proceeds to the Company of approximately $1.9 million. Of this amount, approximately $1.1 million was received during 2019, resulting in approximately $812,000 of stock subscriptions receivable as of December 31, 2019. The remaining $812,000 of proceeds were received and the related Common Stock was issued in January 2020. In accordance with current accounting guidance, the $812,000 of stock subscriptions receivable was included in prepaid and other current assets in the consolidated balance sheet at December 31, 2019.

In June 2019, the Company completed an underwritten public offering of 8,000,000 Shares of our Common Stock pursuant to an Underwriting Agreement between the Company and the Underwriter at a price to the public of $0.75 per share. Of the 8,000,000 total Shares, 4,000,000 shares were placed with the Investor at a price of $0.75 per share. Pursuant to the Underwriting Agreement, the Underwriter purchased the remaining 4,000,000 Shares from the Company at a price of $0.69375 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriter an option (the "Underwriter Option"), exercisable for 30 days, to purchase up to an additional 1,200,000 shares of Common Stock at a price per share of $0.69375. The Underwriter Option was not exercised. The Company paid the Underwriter (a) a commission equal to 7.5% of the gross proceeds from the Shares sold to the Underwriter, (b) a management fee equal to 1.0% of the gross proceeds raised in the offering, (c) $50,000 for non-accountable expenses, (d) $100,000 for fees and expenses of legal counsel to the Underwriter and other out-of-pocket expenses, and (e) $10,000 for clearing expenses. After underwriting discounts, commissions, fees and expenses paid to the Underwriter, the Company received net proceeds from the offering of $5,555,000. The Company paid an additional $127,000 for legal and professional services related to this offering, which further reduced the net proceeds from the offering.

During September 2018, the Company entered into a Stock Purchase Agreement with an investor, pursuant to which the Company issued to the investor in a private placement (the "Private Placement") 18,320,610 shares (the "Securities") of the Company's Common Stock, at a purchase price of $3.0 million (the "Purchase Price"). 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.

During November 2018, the Company issued 925,000 shares of Common Stock to Dr. Goldberg in connection with the Goldberg Agreement. Of those shares, 250,000 are being held in escrow pursuant to the Goldberg Agreement. See Note 14.

During the year ended December 31, 2018, we issued 55,938 shares of our Common Stock valued at $317,000 to our employees as payments in lieu of cash for their 2017 bonuses. No such stock bonus payments were made during the year ended December 31, 2019.

During the years ended December 31, 2019 and 2018, we issued 8,128 and 4,734 shares of Common Stock as matching contributions to our 401(k) Plan which were valued at $20,000 and $36,000, respectively.

b. **Stock Warrants:** Pursuant to the Underwriting Agreement related to the June 2019 public offering, the Company issued to the Underwriter Series OO Warrants to purchase 600,000 shares of Common Stock, representing 7.5% of the aggregate number of shares of Common Stock sold in the offering. The Series OO Warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending five years from the date of the execution of the Underwriting Agreement, at a price per share equal to $0.9375 (125% of the offering price to the public per share). The Series OO Warrants had an estimated fair value of $261,000 at the date of issuance, which was recorded in additional paid-in capital as a reduction of the gross proceeds raised in the public offering. The assumptions used to calculate fair value of the Series OO Warrants included volatility of 88.6%, a risk-free rate of 1.8% and expected dividends of $0.

At December 31, 2019, there are 1.4 million warrants outstanding to purchase Common Stock. The warrants are exercisable at prices ranging from $0.20 to $49.80 per share with a weighted average exercise price per share of $13.26. The warrants have remaining outstanding terms ranging from 1.2 to 15.6 years.

The following table summarizes information about our outstanding warrants at December 31, 2019.

	Exercise Price		Number of Warrants	Expiration Date
Series HH	$ 49.80		15,060	6/25/2023
Series KK	38.36		19,550	3/4/2021
Series LL	0.20		218,264	8/20/2035
Series NN	30.00		550,000	3/3/2022
Series OO	0.9375		600,000	6/13/2024
Total warrants	$ 13.26	*	1,402,874	

* Weighted average exercise price.

In addition, at December 31, 2019, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at $2,000 per share and expire in March 2020.

c. **Common Stock Reserved:** As of December 31, 2019, we have reserved 1,641,344 shares of authorized Common Stock for the exercise of all outstanding stock options and warrants, and 902,162 shares for the issuance of Common Stock pursuant to the December 2019 Stock Purchase Agreement. An additional 250,000 shares of Common Stock have been reserved for issuance to Dr. Goldberg related to the Goldberg Agreement. See Note 14.

16. Income Taxes

As of December 31, 2019 and 2018, our deferred tax assets ("DTAs") were approximately $43.6 million and $41.6 million, respectively. The components of our deferred tax assets are summarized as follows:

	As of December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 31,966,658	$ 29,597,313
R&D credit carryforwards	9,150,580	9,067,874
AMT credit carryforward	310,620	621,240
Stock compensation	382,016	375,731
Intangibles	610,783	550,797
Disallowed interest expense	857,648	878,929
Temporary differences	333,728	480,888
Deferred tax assets before valuation allowance	43,612,033	41,572,772
Valuation allowance	(43,301,413)	(40,951,532)
Net deferred tax assets	$ 310,620	$ 621,240

Current accounting standards require a valuation allowance against DTAs if, based on the weight of available evidence, it is more likely than not that some or all of the DTAs may not be realized. Due to the uncertainty surrounding the realization of these DTAs in future tax returns, all of the DTAs have been fully offset by a valuation allowance at December 31, 2019 and 2018 except the alternative minimum tax ("AMT") credit carryforward amount described below.

In assessing the realizability of DTAs, management considers whether it is more likely than not that some portion or all of the DTAs will not be realized. The ultimate realization of DTAs is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods) and projected future taxable income in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the DTAs are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences or tax carryforwards as of December 31, 2019, except for the AMT credit carryforward.

The Tax Cuts and Jobs Act (the "Tax Act") was signed into law on December 22, 2017. The Tax Act reduced the U.S. federal corporate tax rate from 35% to 21%, effective January 1, 2018. Consequently, we recorded a decrease related to DTAs of $26.4 million with a corresponding net adjustment to a valuation allowance of $26.4 million for the year ended December 31, 2018. The Tax Act repeals the AMT for corporations, and permits any existing AMT credit carryforwards to be used to reduce the regular tax obligation in 2018, 2019 and 2020. Companies may continue using AMT credits to offset any regular income tax liability in years 2018 through 2020, with 50% of remaining AMT credits refunded in each of the 2018, 2019 and 2020 tax years, and all remaining credits refunded in tax year 2021. This results in full realization of an existing AMT credit carryforward irrespective of future taxable income. Accordingly, the Company recorded AMT credit carryforwards of $621,000 and $1.2 million as of December 31, 2019 and 2018, respectively, 50% of which was included in prepaid and other current assets, and 50% of which was included in other noncurrent assets as of December 31, 2019 and 2018.

As of December 31, 2019 and 2018, we had U.S. net operating loss carryforwards of approximately $142.2 million and $130.9 million, respectively. Of those amounts, $15.1 million relates to stock-based compensation tax deductions in excess of book compensation expense ("APIC NOLs") as of December 31, 2019, that will be credited to additional paid-in capital when such deductions reduce taxes payable as determined on a "with-and-without" basis. Accordingly, these APIC NOLs will reduce federal taxes payable if realized in future periods, but NOLs related to such benefits are not included in the table above. As of December 31, 2017, we adopted ASU 2016-09 and thereby eliminated all APIC NOLs with a full offset to a valuation allowance.

As of December 31, 2019 and 2018, we also had state net operating loss carryforwards of approximately $20.1 million and $20.3 million, respectively. The state net operating loss carryforwards will begin expiring in 2032.

At December 31, 2019 and 2018, we had U.S. R&D credit carryforwards of approximately $8.8 million and $8.7 million, respectively.

There were no expirations of U.S. NOL carryforwards during 2019 or 2018. U.S. R&D credit carryforwards of $130,000 and $1.2 million expired during 2019 and 2018, respectively.

The details of our U.S. net operating loss and federal R&D credit carryforward amounts and expiration dates are summarized as follows:

		As of December 31, 2019	
Generated	Expiration	U.S. Net Operating Loss Carryforwards	U.S. R&D Credit Carryforwards
2000	2020	$ —	$ 71,713
2001	2021	—	39,128
2002	2022	—	5,350
2003	2023	—	2,905
2004	2024	—	22,861
2005	2025	—	218,332
2006	2026	—	365,541
2007	2027	—	342,898
2008	2028	—	531,539
2009	2029	—	596,843
2010	2030	—	1,094,449
2011	2031	—	1,950,744
2012	2032	18,850,484	468,008
2013	2033	37,450,522	681,772
2014	2034	34,088,874	816,116
2015	2035	25,073,846	492,732
2016	2036	15,581,209	262,257
2017	2037	—	387,892
2018	2038	—	197,547
2019	N/A	11,138,102	213,065
Total carryforwards		$ 142,183,037	$ 8,761,692

Under Sections 382 and 383 of the Internal Revenue Code ("IRC") of 1986, as amended, the utilization of U.S. net operating loss and R&D tax credit carryforwards may be limited under the change in stock ownership rules of the IRC. The Company completed a Section 382 analysis in 2017 and does not believe a Section 382 ownership change has occurred since then that would impact utilization of the Company's net operating loss and R&D tax credit carryforwards.

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

	2019		2018	
	Amount	%	Amount	%
Benefit at statutory rate	$ (2,299,122)	(21.0)%	$ (3,383,491)	(21.0)%
Adjustments to valuation allowance	2,355,947	21.5%	2,458,580	15.3%
Adjustments to R&D credit carryforwards	(82,706)	(0.8)%	975,840	6.1%
Permanent items and other	26,588	0.3%	(60,682)	(0.3)%
Provision (benefit) per financial statements	$ 707		$ (9,753)	

See Note 1(p).

17. Segments

We report information about our operating segments using the "management approach" in accordance with current accounting standards. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. 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 (sublicensed in April 2018), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform.

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

Year Ended December 31, 2019	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 16,665	$ —	$ —	$ 16,665
License revenue	9,953	—	—	9,953
Grant and other revenue	384,776	246,432	—	631,208
Total revenue	411,394	246,432	—	657,826
Cost of revenue	6,667	—	—	6,667
Research and development expenses, excluding depreciation and amortization	4,795,445	542,822	—	5,338,267
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	16,990	6,113,907	6,130,897
Depreciation and amortization (2)	—	—	144,512	144,512
Loss from operations (3)	(4,390,718)	(313,380)	(6,258,419)	(10,962,517)
Other income (4)	—	—	17,675	17,675
Provision for income taxes	(284)	(20)	(403)	(707)
Loss from continuing operations	(4,391,002)	(313,400)	(6,241,147)	(10,945,549)
Loss from discontinued operations, net of tax effect	(2,665)	—	—	(2,665)
Net loss	(4,393,666)	(313,400)	(6,241,147)	(10,948,214)
Total assets, net of depreciation and amortization:				
United States	$ 55,229	$ 31,449	$ 4,064,228	$ 4,150,906
International	—	—	—	—
Capital expenditures	—	—	1,258	1,258

Year Ended December 31, 2018	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 15,347	$ —	$ —	$ 15,347
License revenue	307,174	—	—	307,174
Grant and other revenue	494,997	351,833	—	846,830
Total revenue	817,518	351,833	—	1,169,351
Cost of revenue	96,636	—	—	96,636
Research and development expenses	3,064,115	1,157,766	—	4,221,881
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	78,606	7,469,144	7,547,750
Depreciation and amortization (2)	—	—	150,385	150,385
Loss from operations (3)	(2,343,233)	(884,539)	(7,619,529)	(10,847,301)
Other expense (4)	—	—	(5,321,270)	(5,321,270)
Benefit from income taxes	1,413	534	7,806	9,753
Loss from continuing operations	(2,341,820)	(884,005)	(12,932,993)	(16,158,818)
Income from discontinued operations, net of tax effect	1,449	—	—	1,449
Gain on sale of discontinued operations, net of tax effect	43,053	—	—	43,053
Net loss	(2,297,318)	(884,005)	(12,932,993)	(16,114,316)
Total assets, net of depreciation and amortization:				
United States	$ 91,425	24,763	6,878,129	6,994,317
International	14,330		381	14,711
Capital expenditures	—	—	46,192	46,192

(1) General and administrative expenses, excluding depreciation and amortization, represent costs that relate to the general administration of the Company and as such are not currently allocated to our individual reportable segments, other than those expenses directly incurred by MT.

(2) Depreciation and amortization is reflected in selling, general and administrative expenses ($144,512 and $150,385 for the years ended December 31, 2019 and 2018, respectively).

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

(4) Amounts consist primarily of losses on debt extinguishment, interest income and interest expense, which are not currently allocated to our individual reportable segments.

18. Agreements

a. License Agreements: In January 2002, we completed a license agreement with the University of California, San Diego ("UCSD") for the exclusive world-wide rights to Tc99m tilmanocept. The license agreement was effective until the later of the expiration date of the longest-lived underlying patent. In July 2014, we amended the license agreement to extend the agreement until the third anniversary of the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD granted us the exclusive rights to make, use, sell, offer for sale and import licensed products as defined in the agreement and to practice the defined licensed methods during the term of the agreement. We could also sublicense the patent rights, subject to certain sublicense terms as defined in the agreement. In consideration for the license rights, we agreed to pay UCSD a license issue fee of $25,000 and license maintenance fees of $25,000 per year. We also agreed to make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a $25,000 minimum annual royalty. In addition, we agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets.

In connection with the March 2017 closing of the Asset Sale to Cardinal Health 414, the Company amended and restated its Tc99m tilmanocept license agreement with UCSD pursuant to which UCSD granted a license to the Company to exploit certain intellectual property rights owned by UCSD and, separately, Cardinal Health 414 entered into a license agreement with UCSD pursuant to which UCSD granted a license to Cardinal Health 414 to exploit certain intellectual property rights owned by UCSD for Cardinal Health 414 to sell Tc99m tilmanocept in the United States, Canada and Mexico. Total costs related to the UCSD license agreement for net sales and royalties of Tc99m tilmanocept outside the United States, Canada and Mexico were $2,000 and $1,000 in 2019 and 2018, respectively, and were recorded in cost of revenue. Total costs related to the UCSD license agreement for annual maintenance fees, milestones and patent-related costs were $191,000 and $35,000 in 2019 and 2018, respectively, and were recorded in research and development expenses.

In July 2014, the Company executed an expanded license agreement for the exclusive world-wide rights to all diagnostic and therapeutic uses of tilmanocept (other than Tc99m tilmanocept used in lymphatic mapping). The license agreement is effective until the third anniversary of the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD has granted us the exclusive rights to make, use, sell, offer for sale and import licensed products as defined in the agreement and to practice the defined licensed methods during the term of the agreement. We may also sublicense the patent rights, subject to certain sublicense terms as defined in the agreement. As consideration for the license rights, we agreed to pay UCSD a license issue fee of $25,000 and license maintenance fees of $25,000 per year. We also agreed to make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a $25,000 minimum annual royalty. In addition, we agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets. Total costs related to the UCSD license agreement for tilmanocept were $355,000 and $250,000 in 2019 and 2018, respectively, and were recorded in research and development expenses.

In December 2011, we executed a license agreement with AstraZeneca AB for NAV4694, a proprietary compound that is primarily intended for use in diagnosing Alzheimer's disease and other CNS disorders. The license agreement is effective until the later of the tenth anniversary of the first commercial sale of NAV4694 or the expiration of the underlying patents. Under the terms of the license agreement, AstraZeneca granted us an exclusive worldwide royalty-bearing license for NAV4694 with the right to grant sublicenses. In consideration for the license rights, we paid AstraZeneca a license issue fee of $5.0 million upon execution of the agreement. We also agreed to pay AstraZeneca up to $6.5 million in contingent milestone payments based on the achievement of certain clinical development and regulatory filing milestones, and up to $11.0 million in contingent milestone payments due following receipt of certain regulatory approvals and the initiation of commercial sales of the licensed product. In addition, we agreed to pay AstraZeneca a royalty on net sales of licensed and sublicensed products. In April 2018, the Company executed a sublicense agreement to provide 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. Total costs related to the AstraZeneca license agreement were $0 in both 2019 and 2018.

b. Employment Agreements: As of December 31, 2019, we had an employment agreement with one of our senior officers. The employment agreement contains termination and/or change in control provisions that would entitle the officer to approximately four times his annual salary and vest outstanding restricted stock and options to purchase Common Stock if there is a termination without cause or change in control of the Company (as defined) and his employment terminates. As of December 31, 2019, our maximum contingent liability under this agreement in such an event is approximately $2.0 million. The employment agreement generally also provides for severance, disability and death benefits.

19. Employee Benefit Plan

We maintain an employee benefit plan under Section 401(k) of the IRC. The plan allows employees to make contributions and we may, but are not obligated to, match a portion of the employee's contribution with our Common Stock, up to a defined maximum. We also pay certain expenses related to maintaining the plan. We recorded expenses related to our 401(k) plan of $14,000 and $40,000 during 2019 and 2018, respectively.

20. Supplemental Disclosure for Statements of Cash Flows

We paid interest aggregating $8,000 in both 2019 and 2018. During 2019 and 2018, we issued 8,128 and 4,734 shares of Common Stock, respectively, as matching contributions to our 401(k) Plan which were valued at $20,000 and $36,000, respectively. In November 2019, we prepaid $349,000 of insurance premiums through the issuance of a note payable to FIF with an interest rate of 5.0%. In November 2018, we prepaid $393,000 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 5.1%. As discussed in Notes 12 and 14, in November 2018, the Company issued 925,000 shares of Common Stock of Navidea to Dr. Goldberg, of which approximately 817,857 million shares valued at $3.2 million were applied as payment of the Platinum debt, including principal and accrued interest of $2.2 million and loss on extinguishment of debt of $1.0 million.

21. Subsequent Events [Update prior to filing if necessary]

On February 13 and 14, 2020, the Company executed agreements with two existing investors to purchase approximately 4.0 million shares of the Company's Common Stock for aggregate gross proceeds to Navidea of approximately $3.4 million.

Also on February 13, 2020, the Company executed a binding term sheet to sell the judgment entered by the Ohio Court of Common Pleas in favor of Navidea in the amount of $4.3 million plus interest, for $4.2 million of proceeds to Navidea. The Company has the option, within 45 days of the sale, to repurchase the Judgment for a 10% premium. Such repurchase option may be in the form of the Company's Common Stock at a 10% discount to the then-current market price.

The Company has evaluated events and transactions subsequent to December 31, 2019 and through the date these consolidated financial statements were included in this Annual Report on Form 10-K and filed with the SEC.

DESCRIPTION OF SECURITIES

General

The following description of our capital stock is only a summary and is subject to the provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which are filed as exhibits to the report to which this exhibit is attached.

Our authorized capital stock consists of:

- 300,000,000 shares of common stock, $0.001 par value per share; and
- 5,000,000 shares of undesignated preferred stock, $0.001 par value per share.

Common Stock

Dividends

Subject to the rights and preferences of any outstanding preferred stock, each share of common stock is entitled to receive, when and as declared by the board of directors, out of our available assets at such time, such dividends as may be declared from time to time by the board of directors. We have never paid dividends on our common stock and do not intend to do so in the foreseeable future. We intend to retain any future earnings to finance our growth.

Liquidation

If our company is liquidated, any assets that remain after the creditors are paid, and the owners of preferred stock receive any liquidation preferences, will be distributed to the owners of our common stock pro-rata. Neither the merger or consolidation by us into or with any other corporation, nor the merger or consolidation of any other corporation into or with us, nor the sale, lease, exchange or other disposition (for cash, shares of stock, securities, or other consideration) of all or substantially all our assets, will be deemed to be a dissolution, liquidation, or winding up of our business, whether voluntary or involuntary.

Voting Rights

Each share of our common stock entitles the owner to one vote. There is no cumulative voting. Our directors are elected by a plurality of the votes of the shares present in person or represented by proxy at meetings of our stockholders and entitled to vote in the election of directors.

Preemptive Rights

Owners of our common stock do not have any preemptive rights. We may sell shares of our common stock to third parties without first offering it to current stockholders.

Redemption Rights

We do not have the right to buy back shares of our common stock except in extraordinary transactions such as mergers and court approved bankruptcy reorganizations. Owners of our common stock do not ordinarily have the right to require us to buy their common stock. We do not have a sinking fund to provide assets for any buy back.

Conversion Rights

Shares of our common stock cannot be converted into any other kind of stock except in extraordinary transactions, such as mergers and court approved bankruptcy reorganizations.

Market Information

Our common stock is listed on the NYSE American under the symbol “NAVB.”

Transfer Agent and Registrar

The transfer agent for our common stock is Continental Stock Transfer & Trust Company, located at One State Street, 30th Floor, New York, NY 10004. Their telephone number is (212) 509-4000.

Blank Check Preferred Stock

Our certificate of incorporation authorizes our board of directors to issue "blank check" preferred stock. The board of directors may divide this stock into series and set their rights.

Under the terms of our certificate of incorporation, our board of directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to determine and alter all rights, preferences, and privileges and qualifications, limitations, and restrictions thereof (including, without limitation, voting rights and the limitation and exclusion thereof).

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could make it more difficult for a third party to acquire, or could adversely affect the rights of our common stockholders by restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock or delaying or preventing a change in control without further action by the stockholders. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our common stock.

As of March 2, 2020, no shares of preferred stock were issued and outstanding. All shares of preferred stock offered hereby will, when issued, be fully paid and non-assessable and, unless otherwise stated in a prospectus supplement relating to the series of preferred stock being offered, will not have any preemptive or similar rights. We will set forth in a prospectus supplement relating to the class or series of preferred stock being offered the specific terms of each series of our preferred stock, including the price at which the preferred stock may be purchased, the number of shares of preferred stock offered, and the terms, if any, on which the preferred stock may be convertible into common stock or exchangeable for other securities.

Anti-Takeover Charter Provisions and Laws

Some features of our certificate of incorporation and bylaws and the Delaware General Corporation Law (the "*DGCL*"), which are further described below, may have the effect of deterring third parties from making takeover bids for control of our company or may be used to hinder or delay a takeover bid. This would decrease the chance that our stockholders would realize a premium over market price for their shares of common stock as a result of a takeover bid. See the section entitled "Risk Factors".

Limitations on Stockholder Actions

Our certificate of incorporation provides that stockholder action may only be taken at a meeting of the stockholders. Thus, an owner of a majority of the voting power could not take action to replace the board of directors, or any class of directors, without a meeting of the stockholders, nor could he amend the bylaws without presenting the amendment to a meeting of the stockholders. Furthermore, under the provisions of the certificate of incorporation and bylaws, only the board of directors has the power to call a special meeting of stockholders. Therefore, a stockholder, even one who owns a majority of the voting power, may neither replace sitting board of directors members nor amend the bylaws before the next annual meeting of stockholders.

Advance Notice Provisions

Our bylaws establish advance notice procedures for the nomination of candidates for election as directors by stockholders, as well as for other stockholder proposals to be considered at annual meetings. Generally, we must receive a notice of intent to nominate a director or raise any other matter at a stockholder meeting not less than 120 days before the first anniversary of the mailing of our proxy statement for the previous year's annual meeting. The notice must contain required information concerning the person to be nominated or the matters to be brought before the meeting and concerning the stockholder submitting the proposal.

Delaware Law

We are incorporated in Delaware, and as such are subject to Section 203 of the DGCL, which provides that a corporation may not engage in any business combination with an interested stockholder during the three years after the stockholder becomes an interested stockholder unless:

- the corporation's board of directors approved in advance either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85 percent of the corporation's voting stock at the time the transaction commenced; or
- the business combination is approved by the corporation's board of directors and the affirmative vote of at least two-thirds of the voting stock which is not owned by the interested stockholder.

An interested stockholder is anyone who owns 15% or more of a corporation's voting stock, or who is an affiliate or associate of the corporation and was the owner of 15% or more of the corporation's voting stock at any time within the previous three years; and the affiliates and associates of any those persons. Section 203 of the DGCL makes it more difficult for an interested stockholder to implement various business combinations with our Company for a three-year period, although our stockholders may vote to exclude it from the law's restrictions.

Classified Board

Our certificate of incorporation and bylaws divide our board of directors into three classes with staggered three-year terms. There are currently four directors. Two classes are comprised of two directors each and a third class is currently vacant. At each annual meeting of stockholders, the terms of one class of directors will expire and the newly nominated directors of that class will be elected for a term of three years. The board of directors will be able to determine the total number of directors constituting the full board of directors and the number of directors in each class, but the total number of directors may not exceed nine nor may the number of directors in any class exceed six. No reduction in the total number of directors or in the number of directors in a given class will have the effect of removing a director from office or reducing the term of any then-sitting director. Stockholders may only remove directors for cause. If the board of directors increases the number of directors in a class, it will be able to fill the vacancies created for the full remaining term of a director in that class even though the term may extend beyond the next annual meeting. The directors will also be able to fill any other vacancies for the full remaining term of the director whose death, resignation or removal caused the vacancy.

A person who has a majority of the voting power at a given meeting will not in any one year be able to replace a majority of the directors since only one class of the directors will stand for election in any one year. As a result, at least two annual meeting elections will be required to change the majority of the directors by the requisite vote of stockholders. The purpose of classifying the board of directors is to provide for a continuing body, even in the face of a person who accumulates a sufficient amount of voting power, whether by ownership or proxy or a combination, to have a majority of the voting power at a given meeting and who may seek to take control of our Company without paying a fair premium for control to all of the owners of our common stock. This will allow the board of directors time to negotiate with such a person and to protect the interests of the other stockholders who may constitute a majority of the shares not actually owned by that person. However, it may also have the effect of deterring third parties from making takeover bids for control of our Company or may be used to hinder or delay a takeover bid.

STOCK PURCHASE AGREEMENT

This Stock Purchase Agreement (this "***Agreement***") is made and entered into as of February 14, 2020, by and between Navidea Biopharmaceuticals, Inc., a Delaware corporation (the "***Company***"), and Keystone Capital Partners LLC (the "***Investor***").

WHEREAS, the Company desires to sell to the Investor, and the Investor desires to purchase from the Company, US$1,400,000 in shares (the "***Securities***") of the Company's common stock, par value $0.001 per share (the "***Common Stock***"), subject to the terms and conditions set forth in this Agreement and pursuant to a currently effective shelf registration statement on Form S-3 (Registration Number 333-222092) (the "***Registration Statement***"), as supplemented by the Prospectus Supplement (as defined below), which Registration Statement has been declared effective in accordance with the Securities Act of 1933, as amended (the "***Securities Act***"), by the United States Securities and Exchange Commission (the "***SEC***").

NOW, **THEREFORE**, in consideration of the foregoing and the mutual representations, warranties, covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Investor hereby agree as follows:

1. Definitions. As used in this Agreement, unless the context otherwise requires, the following terms shall have the respective meanings specified or referred to in this Section 1:

"***Affiliate***" means, when used with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, controls or is controlled by or is under common control with the Person specified. For purposes of this definition, "control," when used with respect to any Person, means the power to direct the management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise. The terms "controlling" and "controlled" have meanings correlative to the foregoing.

"***Court Order***" means any judgment, order, award or decree of any foreign, federal, state, local or other court or administrative or regulatory body and any award in any arbitration proceeding.

"***Encumbrance***" means any lien (statutory or other), encumbrance, claim, charge, security interest, mortgage, deed of trust, pledge, hypothecation, assignment, conditional sale or other title retention agreement, preference, priority or other security agreement or preferential arrangement of any kind or nature, and any easement, encroachment, covenant, restriction, right of way, defect in title or other encumbrance of any kind.

"***Execution Date***" means the date upon which this Agreement has been executed by both Parties.

"***Governmental Body***" means any foreign, federal, state, local or other government, governmental, statutory or administrative authority or regulatory body, self-regulatory organization or any court, tribunal or judicial or arbitral body.

"***Person***" means any individual, partnership, corporation, limited liability company, association, joint venture, joint-stock company, trust, unincorporated organization, Governmental Body or other entity.

"***Requirements of Law***" means any applicable foreign, federal, state and local laws, statutes, regulations, rules, codes, ordinances, Court Orders and requirements enacted, adopted, issued or promulgated by any Governmental Body or common law or any applicable consent decree or settlement agreement entered into with any Governmental Body.

"***SEC Reports***" means, collectively, all reports of the Company required to be filed by it under the Securities Act and the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), including pursuant to Section 13(a) or 15(d) thereof, for the twelve months preceding the date hereof. The term "SEC Reports" shall not include any proxy statement (or amendment or supplement thereto) filed or prepared by the Company.

2. Purchases of Common Stock.

(a) Subscription. Subject to the terms and conditions hereof, the Investor hereby irrevocably subscribes for the Securities for the aggregate purchase price of US$1,400,000 (the "***Purchase Price***"), which is issuable and payable as described in Section 4.

(b) Compliance with NYSE American Rules. Notwithstanding anything in this Agreement to the contrary, unless permitted by the applicable rules and regulations of the NYSE American, the total number of shares of Common Stock that may be issued under this Agreement, shall not exceed the aggregate number of shares of Common Stock that the Company may issue without breaching the Company's obligations under the rules or regulations of the NYSE American (the number of shares that may be issued without violating such rules and regulations, the "***NYSE Cap***"). Notwithstanding the foregoing, such limitation shall not apply in the event that the Company obtains the approval of its stockholders as required by the applicable rules of the NYSE American for issuances of shares of Common Stock in excess of such amount the NYSE Cap, and shall also be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. The Company may, in its sole discretion, determine whether to obtain stockholder approval to issue more shares of Common Stock hereunder than is permitted by the NYSE Cap if such issuance would require stockholder approval under the rules or regulations of the NYSE American.

(c) Beneficial Ownership Limitation. The Company shall not issue, and an Investor shall not purchase, any shares of Common Stock under this Agreement, if such shares proposed to be issued and sold, when aggregated with all other shares of Common Stock then owned beneficially (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder) by the Investor and its affiliates would result in the beneficial ownership by the Investor and its affiliates of more than 33.3% of the then issued and outstanding shares of Common Stock.

3. Use of Proceeds. The Company intends to use the net proceeds received from the sale of the Securities or otherwise pursuant to this Agreement for general working capital purposes, including, without limitation, on product development and commercialization, development of intellectual property, purchases of inventory, sales and marketing, repayment of principal and interest on outstanding indebtedness, and other operating expenses.

4. Closing.

(a) Closing. The closing of the sale and purchase of the Securities (the "***Closing***") shall occur on such date and time as agreed upon by the parties hereto (the "***Closing Time***"). At Closing Time, the Company shall deliver to the Investor the Securities against payment by the Investor of the Purchase Price for the Securities in accordance with Sections 4(b) and (c) below.

(b) Payment for Securities. At each Closing, the Investor shall pay to the Company an amount equal to the proportion of the Purchase Price for the number of Securities to be purchased at such Closing Time payable as full payment for the Securities issuable at that Closing via wire transfer of immediately available funds in accordance with the wiring instructions attached hereto as Appendix A or as otherwise designated by the Company, by check payable to the Company, or by any combination of such methods.

(c) Purchase Price. The per share purchase price with respect to the Investor shall be $.85 (Eighty-Five Cents) per share.

(d) Administrative Fee. In consideration for the Investor's underlying fees and expenses, the Issuer shall deliver to the Investor on the Execution Date a fee in the amount of $150,000 (One Hundred Fifty Thousand dollars).

5. Representations and Warranties of the Company. As of the date hereof and as of the Closing Time, the Company represents and warrants that:

(a) Organization. The Company is duly incorporated or formed and validly existing and in good standing under the law of its jurisdiction of incorporation or formation. The Company is duly qualified and in good standing as a foreign company in each other jurisdiction in which it owns or leases property or in which the conduct of its business requires it to be so qualified or licensed, except where the failure to be so qualified and in good standing would not, individually or in the aggregate, have or reasonably be expected to have a material adverse effect on the business, properties, financial condition, results of operations, or prospects of the Company (a "***Material Adverse Effect***").

(b) Authorization. The Company has all requisite power and authority to execute and deliver this Agreement and to perform its obligations hereunder in accordance with the terms hereof. The execution, delivery and performance of this Agreement by the Company have been duly authorized by all necessary corporate action. This Agreement has been duly executed and delivered by the Company, and this Agreement constitutes the legal, valid and binding obligation of the Company enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws relating to or affecting the enforcement of creditors' rights generally and by general equitable principles.

(c) No Violation; Consents and Approvals. The execution and delivery by the Company of this Agreement does not, and the consummation by the Company of any of the transactions contemplated hereby and compliance by the Company with the terms, conditions and provisions hereof (including the offer and sale of the Securities by the Company) will not conflict with, violate, result (with the giving of notice or passage of time or both) in a breach of the terms, conditions or provisions of, or constitute a default, an event of default or an event creating rights of acceleration, termination or cancellation or a loss of rights under, or result in the creation or imposition of any Encumbrance upon any of the assets or properties of the Company under (A) the certificate of incorporation or certificate of formation or the by-laws, each as applicable, of the Company, (B) any note, instrument, agreement, contract, mortgage, lease, license, franchise, guarantee, permit or other authorization, right, restriction or obligation to which the Company is a party or any of their respective assets or properties is subject or by which the Company is bound, (C) any Court Order to which the Company is a party or any of their respective assets or properties is subject or by which the Company is bound, or (D) any Requirements of Law applicable to the Company or any of their respective assets or properties.

(d) Capitalization. The Securities will be duly authorized, and when issued in accordance with this Agreement, (i) will be validly issued, fully paid and non-assessable and will be free and clear of any Encumbrances (other than, with respect to the Investor, any Encumbrances created by or through the Investor and restrictions on transfer imposed by the Securities Act (if any), and applicable "blue sky" or other similar laws of the Investor's state of residence (if any) (referred to as the "***State Securities Laws***")) and the Investor will have good title thereto and (ii) will not have been issued in violation of any preemptive or subscription rights and will not result in the anti-dilution provisions of any security of the Company becoming applicable.

(e) Compliance with Laws. Except as may otherwise be described in the SEC Reports, the Company is in compliance with all laws and regulatory requirements to which it is subject, including U.S. sanctions laws and the Foreign Corrupt Practices Act, 15 U.S.C. §78 et seq., as it may be amended from time to time, except for such non-compliance that (A) could not reasonably be expected to have a Material Adverse Effect or (B) occurs as a result of any proceedings or investigations relating to any matter described in the SEC Reports.

(f) No Restrictions on Common Stock. Except as described in the SEC Reports, (i) No Person has the right, contractual or otherwise, to cause the Company to issue or sell to it any shares of Common Stock or shares of any other capital stock or other equity interests of the Company and (ii) no Person has any purchase option, call option, preemptive rights, resale rights, subscription rights, rights of first refusal or other rights to purchase any shares of Common Stock or shares of any other capital stock of or other equity interests in the Company.

(g) Investment Company; Passive Foreign Investment Company. The Company is not and, after giving effect to the offer and sale of the Securities will not be an "investment company," required to register under the Investment Company Act of 1940, as amended. The Company does not believe that it is a "passive foreign investment company" as such term is defined in the Internal Revenue Code of 1986, as amended from time to time, and the regulations promulgated thereunder (the "***Code***").

(h) Compliance with SEC Filings.

(i) The Company has filed all SEC Reports required to be filed by it with the SEC for the twelve months preceding the date hereof. As of their respective dates or, if amended, as of the date of such amendment, the SEC Reports complied in all material respects with the requirements of the Securities Act, Exchange Act and the Sarbanes-Oxley Act of 2002 and the applicable rules and regulations promulgated thereunder, and none of the SEC Reports included any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act.

(ii) The audited consolidated financial statements and unaudited consolidated financial statements (including all related notes and schedules) of the Company included in the SEC Reports complied as to form in all material respects with the rules and regulations of the SEC then in effect, fairly present in all material respects the consolidated financial position of the Company and its consolidated subsidiaries, as of the respective dates thereof, and the consolidated results of their operations and their consolidated cash flows for the respective periods then ended (subject, in the case of the unaudited statements, to normal recurring year-end audit adjustments that were not or are not expected to be, individually or in the aggregate, materially adverse to the Company), and were prepared in accordance with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis during the periods involved, except as otherwise disclosed in the Company SEC Documents.

(i) Registration and Listing of Common Stock. The class of Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act. The Common Stock is listed on the NYSE American, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the NYSE American. As of the date of this Agreement, except as disclosed in the SEC Reports, the Company has not received any notification that, and has no knowledge that, the SEC is contemplating terminating the Company's registration under Section 12(g) of the Exchange Act.

(j) Registration Statement. The sale of the Common Stock is being made pursuant to the Registration Statement, which was originally filed by the Company with the SEC on December 15, 2017 and declared effective by the SEC on December 27, 2017. The Registration Statement is true and correct in all material respects and do not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading.

6. Representations and Warranties of the Investor. As an inducement to the Company to enter into this Agreement and to consummate the transactions contemplated hereby, the Investor represents and warrants as of the date hereof and as of Closing Time, as follows:

(a) Authorization. Investor has full power and authority to execute and deliver this Agreement and to perform its obligations hereunder in accordance with the terms hereof. The execution and delivery of this Agreement by the Investor and the consummation by it of the transactions contemplated hereby do not conflict with its certificate of incorporation, articles of organization, or operating agreement or similar documents, and do not require further consent or authorization by the Investor, its board of directors, stockholders, partners, managers and/or its members. This Agreement has been, and at or prior to the Closing will have been, duly executed and delivered by the Investor, and constitutes the legal, valid and binding obligation of the Investor, enforceable against the Investor in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws relating to or affecting the enforcement of creditors' rights generally and by general equitable principles.

(b) No Consents Required. No approval, authorization, consent or order of or filing with any federal, state, local or foreign government or regulatory commission, board, body, authority or agency, or of or with any self-regulatory organization, or other non-governmental regulatory authority (including any national securities exchange), is required in connection with the execution, delivery and performance of this Agreement by Investor or the consummation by the Investor of the transactions contemplated hereby, except for such approvals, authorizations, consents, orders or filings that have been obtained or made and are in full force and effect.

(c) No Violation. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby will not conflict with, result in any breach or violation of or constitute a default under (or constitute any event which with notice, lapse of time or both would result in any breach or violation of or constitute a default under or give the holder of any indebtedness (or a Person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under) (or result in the termination of, or in the creation or imposition of a lien, charge or Encumbrance on any property or assets of Investor pursuant to) (i) the organizational or other governing documents of the Investor, (ii) any indenture, mortgage, deed of trust, bank loan or credit agreement or other evidence of indebtedness, or any license, lease, contract or other agreement or instrument to which the Investor is a party or by which the Investor or any of its properties may be bound or affected, (iii) any federal, state, local or foreign law, regulation or rule, (iv) any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including any national securities exchange) or (v) any Court Order applicable to the Investor or any of its properties, except in the case of the foregoing clauses (ii), (iii), (iv) and (v) as would not individually or in the aggregate, materially and adversely affect the Investor's ability to perform its obligations under this Agreement or consummate the transactions contemplated herein on a timely basis.

(d) Accredited Investor and Qualified Institutional Buyer.

(i) Investor is acquiring the Securities to be issued under this Agreement to Investor for its own account, not as nominee or agent, with the present intention of holding such securities for purposes of investment, and not with the view to the public resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the U.S. federal securities laws or any applicable State Securities Laws. Investor is purchasing and holding any purchased Securities for its own account and is not party to any co-investment, joint venture, partnership or other understandings or arrangements with any other party relating to the Securities or any other transactions contemplated hereunder.

(ii) Investor is an "accredited investor" as such term is defined in Rule 501(a) of Regulation D under the Securities Act or a "qualified institutional buyer" within the meaning of Rule 144A under the Securities Act and a "qualified purchaser" as defined in Section 2(a)(51)(A) of the Investment Company Act of 1940, as amended.

(iii) Investor acknowledges that it has completed the Investor Questionnaire contained in Appendix B and that the information contained therein is complete and accurate as of the date thereof and is hereby affirmed as of the Closing Time. Any information that has been furnished or that will be furnished by Investor to evidence its status as an accredited investor is accurate and complete, and does not contain any misrepresentation or material omission.

(iv) Investor has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Company, and has so evaluated the merits and risks of such investment, and understands that it may be required to bear the risks thereof. Investor has previously invested in securities similar to the Securities and fully understands the limitations on transfer and restrictions on sales of the Securities. Investor represents that it is able to bear the economic risk of its investment in the Securities and is able to afford the complete loss of any such investment.

(v) Investor has conducted its own independent evaluation, made its own analysis and consulted with advisors as it has deemed necessary, prudent, or advisable in order for the Investor to make its own determination and decision to enter into the transactions contemplated by this Agreement and to execute and deliver this Agreement.

(vi) Investor has reviewed the SEC Reports (including all disclosures related to the potential delisting of the Common Stock from the NYSE American exchange if Navidea does not regain compliance with the continued listing requirements of the NYSE American exchange by February 14, 2020 (the "***Potential Delisting***")) and is familiar with the business and financial condition and operations of the Company. Investor has had an opportunity to discuss the Potential Delisting and the terms and conditions of the offering of the Securities with the Company's management to enable it to evaluate the transactions contemplated by this Agreement and to make an informed investment decision concerning the Securities, and Investor has had the opportunity to obtain and review information reasonably requested by the Investor.

(vii) Investor is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or, to the Investor's knowledge, any other general solicitation or general advertisement. Neither Investor nor its Affiliates or any person acting on its or any of their behalf has engaged, or will engage, in any form of general solicitation or general advertising (within the meaning of Rule 502(c) under the Securities Act) in connection with the offering of the Securities.

(viii) Investor has sufficient cash on hand or other immediately available funds to pay the aggregate Purchase Prices and otherwise satisfy its obligations in connection with this Agreement and the transactions contemplated hereby.

(ix) Investor is not subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) through (viii) under the Securities Act, except for Disqualification Events covered by Rule 506(d)(2)(ii) or (iii) under the Securities Act and disclosed in writing in reasonable detail to the Company.

(e) No Broker's Fees. No brokerage or finder's fees or commissions are or will be payable by the Investor or any of its Affiliates or subsidiaries (if applicable) to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the issuance of the Securities, and Investor has not taken any action that could cause the Company to be liable for any such fees or commissions.

(f) Advisors. Investor acknowledges that, prior to entering into this Agreement, it was advised by Persons deemed appropriate by Investor concerning this Agreement and the transactions contemplated hereunder and conducted its own due diligence investigation (including with respect to the Potential Delisting) and made its own investment decision with respect to this Agreement, the transactions contemplated hereunder and the purchase of the Securities.

(g) Arm's Length Transaction. Investor is acting solely in the capacity of an arm's length contractual counterparty to the Company with respect to the transactions contemplated hereby. Additionally, without derogating from or limiting the representations and warranties of the Company, Investor (i) is not relying on the Company for any legal, tax, investment, accounting or regulatory advice; (ii) has consulted with its own advisors concerning such matters; and (iii) shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby.

(h) No Further Reliance. Investor acknowledges that it is not relying upon any representation or warranty made by the Company that is not set forth in this Agreement or in the Company's public filings. Investor confirms that the Company has not (i) given any guarantee or representation as to the potential success, return, effect or benefit (either legal, regulatory, tax, financial, accounting or otherwise) of an investment in the Securities; (ii) made any representation to the Investor regarding the legality of an investment in the Securities under applicable legal investment or similar laws or regulations, except as set forth herein; or (iii) the likelihood or ability of the Company to regain compliance with the continued listing requirements of the NYSE American exchange or continue trading on a national securities exchange. Investor confirms that (A) it has conducted a review and analysis of the business, assets, condition, operations and prospects of the Company, and the terms of the Securities, and has access to such financial and other information regarding the Company, in each case that the Investor considers sufficient for purposes of the purchase of the Securities; (B) at a reasonable time prior to its purchase of the Securities, it had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Securities and to obtain additional information necessary to verify any information furnished to the Investor or to which the Investor had access; and (C) it has not received any offering memorandum or offering document in connection with the offering of the Securities.

(i) No ERISA Plans. Either (a) Investor is not purchasing or holding Securities (or any interest in Securities) with the assets of (i) an employee benefit plan that is subject to Title I of ERISA, (ii) a plan, individual retirement account or other arrangement that is subject to Section 4975 of the Code, (iii) an entity whose underlying assets are considered to include "plan assets" of any of the foregoing by reason of such plan's, account's or arrangement's investment in such entity, or (iv) a governmental, church, non-U.S. or other plan that is subject to any similar laws; or (b) the purchase and holding of such Securities by the Investor, throughout the period that it holds such Securities, and the disposition of such Securities or an interest therein will not constitute (x) a non-exempt prohibited transaction under Section 406 of ERISA or Section 4975 of the Code, (y) a breach of fiduciary duty under ERISA or (z) a similar violation under any applicable similar laws.

7. Reserved.

8. Conditions to Obligations of the Company. The obligation of the Company to sell and issue the Securities to the Investor at the Closing Time is subject to the fulfillment on or before the Closing Time of the following conditions, any of which may be waived (in whole or in part) by the Company in its sole discretion:

(a) No Injunction. As of the Closing Time, no Governmental Body nor any other Person shall have issued an order, injunction, judgment, decree, ruling or assessment which shall then be in effect restraining or prohibiting the completion of the transactions contemplated by this Agreement, nor to the Company's knowledge, shall any such order, injunction, judgment, decree, ruling or assessment be threatened or pending.

(b) Purchase Price Paid. The Investor shall have paid the aggregate Purchase Price to the Company, pursuant to the requirements of this Agreement.

(c) Covenants and Agreements. The Investor shall have performed and complied with the covenants and agreements required to be performed or complied with by the Investor hereunder on or prior to the Closing Time.

(d) Representations and Warranties. The representations and the warranties of the Investor contained in this Agreement shall be true and correct in all material respects as of the Closing Time, with the same effect as though such representations and warranties had been made on and as of such date.

9. Conditions to Obligations of the Investor. The irrevocable obligation of the Investor to pay the Company the aggregate Purchase Price in respect of the Securities to be issued under this Agreement to the Investor is subject solely to the fulfillment of, or, to the extent permitted by law, waiver by, the Investor prior to each Closing Time, as the case may be, of each of the following conditions:

(a) Covenants and Agreements. The Company shall have performed and complied in all material respects with the covenants and agreements required to be performed or complied with by it hereunder on or prior to the Closing Time, as applicable.

(b) Representations and Warranties. The representations and the warranties of the Company contained in this Agreement shall be true and correct in all material respects as of the Closing Time, except with respect to provisions including the terms "material," "Material Adverse Effect" or words of similar import and except with respect to materiality, as reflected under GAAP, and with respect to which such representations and warranties made as of the applicable date, such representations and warranties shall be true and correct only as of such date.

(c) Prospectus Supplement. The Company shall have prepared and filed with the SEC a prospectus supplement containing certain supplemental information regarding the Securities and the terms of the offering contemplated herein.

(d) Listing. The Company has not been delisted from the NYSE American.

10. Miscellaneous.

(a) Survival of Obligations. All representations, warranties, covenants, agreements and obligations contained in this Agreement shall survive (i) the acceptance of the Subscriptions by the Company and the Closing and (ii) the death or disability of the Investor.

(b) Notices. All notices or other communications required or permitted hereunder shall be in writing and shall be deemed given or delivered (i) when delivered personally, (ii) when delivered by electronic mail (so long as notification of a failure to deliver such electronic mail is not received by the sending party), (iii) if transmitted by electronic mail when confirmation of transmission is received by the sending party, (iv) if sent by registered or certified mail, postage prepaid, return receipt requested, on the third business day after mailing or (v) if sent by reputable overnight courier when received; and shall be addressed to the Investor or to the Company as follows:

If to the Company:	Navidea Biopharmaceuticals, Inc. 4995 Bradenton Avenue Suite 240 Dublin, Ohio 43017 Attention: Jed A. Latkin, Chief Executive Officer Email: jlatkin@navidea.com
with a copy to:	Thompson Hine LLP 335 Madison Avenue 12th Floor New York, New York 10017-4611 Attention: Faith L. Charles Email: Faith.Charles@ThompsonHine.com
If to Investor:	139 Fulton St. Suite 412 New York, NY 10038
with a copy to:	Jonathan D. Leinwand, P.A. 18851 NE 29th Ave., Suite 1011 Aventura, FL 33180 Attention: Jonathan Leinwand Email: jonathan@jdlpa.com

Any party hereto may, from time to time, change its address, e-mail address or other information for the purpose of notices to that party by giving notice specifying such change to the other party hereto.

(c) Execution in Counterparts; Effectiveness. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, and shall become binding when one or more counterparts have been signed by and delivered to each of the parties hereto.

(d) Amendments. This Agreement shall not be amended, modified or supplemented except by a written instrument signed by the parties hereto.

(e) Expenses. The Investor shall be responsible for its own costs and expenses in connection herewith, including the fees and expenses, if any, of its advisors and its counsel.

(f) Waiver. Any term or provision of this Agreement may be waived, or the time for its performance may be extended, by the party entitled to the benefit thereof. Any such waiver shall be validly and sufficiently authorized for the purposes of this Agreement if, as to any party, it is in writing signed by an authorized representative of such party. The failure or delay of any party to enforce at any time any provision of this Agreement shall not be construed to be a waiver of such provision, nor in any way to affect the validity of this Agreement or any part hereof or the right of any party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach.

(g) Severability. Wherever possible, each provision hereof shall be interpreted in such manner as to be effective and valid under applicable law, but in case any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such provision shall be ineffective to the extent, but only to the extent, of such invalidity, illegality or unenforceability without invalidating the remainder of such invalid, illegal or unenforceable provision or provisions or any other provisions hereof, unless such a construction would be unreasonable.

(h) Assignment; Successors and Assigns. Neither this Agreement nor any of the rights and obligations of any party hereunder may be assigned, delegated or otherwise transferred by any party hereto without the prior written consent of the other party hereto. No such assignment, delegation or other transfer shall relieve the assignor of any of its obligations or liabilities hereunder. This Agreement shall be binding upon and shall inure to the benefit of the parties and their respective successors and permitted assigns.

(i) No Third Party Beneficiaries. Nothing in this Agreement, express or implied, is intended or shall be construed to confer upon any third Person, other than the parties and their respective successors and assigns permitted by Section 10(h), any right, remedy or claim under or by reason of this Agreement.

(j) Governing Law. This Agreement shall be governed by and construed in accordance with the substantive laws of the State of New York without regard to its conflict of laws principles.

(k) Submission to Jurisdiction. Each of the parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the non-exclusive jurisdiction of the state district courts of the State of New York and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Agreement, or for recognition or enforcement of any judgment, and each of the parties hereto hereby irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in New York or, to the extent permitted by law, in such Federal court. Each of the parties hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Nothing in this Agreement shall affect any right that the Investor may otherwise have to bring any action or proceeding relating to this Agreement against the Company and its subsidiaries or their respective properties in the courts of any jurisdiction or any right that the Company may otherwise have to bring any action or proceeding relating to this Agreement against the Investor or its properties in the courts of any jurisdiction. Each party hereto irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of venue of any such proceeding brought in such a court referred to in the first sentence of this Section 10(k) and any claim that any such proceeding brought in such a court has been brought in an inconvenient forum.

(l) Waiver of Jury Trial. EACH PARTY HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY(WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, TO IT THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

(m) Public Announcements. The Investor shall not make any public announcements or otherwise communicate with the news media with respect to this Agreement or the transactions contemplated hereby without the prior written consent of the Company. The Company and the Investor agree that the Company may issue a press release announcing the Securities offering and disclosing all material terms and conditions of such offering. Notwithstanding the forgoing, the Investor may make or cause to be made any press release or similar public announcement or communication as may be required to comply with (i) the requirements of applicable law, including the Exchange Act or (ii) its disclosure obligations or practices with respect to its investors; *provided* that prior to making any such disclosure under this clause (ii), the Investor shall provide a copy of such proposed disclosure to the Company and shall only publicly make such disclosure with the consent of the Company, which consent shall not be unreasonably withheld or delayed, if the Company has not previously made a public announcement of the transactions contemplated hereby.

(n) Entire Agreement. This Agreement and the Appendices, and the documents delivered pursuant hereto and thereto constitute the entire agreement and understanding among the parties with respect to the subject matter contained herein or therein, and supersede any and all prior agreements, negotiations, discussions, understandings, term sheets or letters of intent between or among of the parties with respect to such subject matter.

(o) Interpretation.

In this Agreement, unless the context clearly indicates otherwise:

(i) words used in the singular include the plural and words in the plural include the singular;

(ii) reference to any gender includes the other gender;

(iii) the word “including” (and with correlative meaning “include”) means “including but not limited to” or “including without limitation”;

(iv) reference to any Section or Appendix means such Section of, or such Appendix to, this Agreement, as the case may be, and reference in any Section or definition to any clause means such clause of such Section or definition;

(v) the words “herein,” “hereunder,” “hereof,” “hereto” and words of similar import shall be deemed references to this Agreement as a whole and not to any particular Section or other provision hereof;

(vi) reference to any agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof and by this Agreement;

(vii) reference to any law (including statutes and ordinances) means such law (including all rules and regulations promulgated thereunder) as amended, modified, codified or reenacted, in whole or in part, and in effect at the time of determining compliance or applicability;

(viii) relative to the determination of any period of time, “from” means “from and including,” “to” means “to but excluding” and “through” means “through and including”; and

(ix) the titles and headings of Sections contained in this Agreement have been inserted for convenience of reference only and shall not be deemed to be a part of or to affect the meaning or interpretation of this Agreement.

(p) This Agreement was negotiated by the parties with the benefit of legal representation, and no rule of construction or interpretation otherwise requiring this Agreement to be construed or interpreted against any party shall apply to any construction or interpretation hereof. Subject to Section 10(g), this Agreement shall be interpreted and construed to the maximum extent possible so as to uphold the enforceability of each of the terms and provisions hereof.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the undersigned has executed this Agreement as of the first date written above.

INVESTOR:

[KEYSTONE CAPITAL PARTNERS LLC]

By: Fredric G. Zaino
Name: Fredric G. Zaino
Title: Manager

[*Signature Page to Stock Purchase Agreement*]

IN WITNESS WHEREOF, the undersigned has executed this Agreement as of the first date written above.

NAVIDEA BIOPHARMACEUTICALS, INC.

By: Jed A. Latkin
Name: Jed A. Latkin
Title: Chief Executive Officer, Chief Financial Officer and Chief Operating Officer

[*Signature Page to Stock Purchase Agreement*]

STOCK PURCHASE AGREEMENT

This Stock Purchase Agreement (this "***Agreement***") is made and entered into as of February 13, 2020, by and between Navidea Biopharmaceuticals, Inc., a Delaware corporation (the "***Company***"), and John Kim Scott (the "***Investor***").

WHEREAS, the Company desires to sell to the Investor, and the Investor desires to purchase from the Company, US$2,017,500 of shares (the "***Securities***") of the Company's common stock, par value $0.001 per share (the "***Common Stock***"), subject to the terms and conditions set forth in this Agreement.

NOW, **THEREFORE**, in consideration of the foregoing and the mutual representations, warranties, covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Investor hereby agree as follows:

1. Definitions. As used in this Agreement, unless the context otherwise requires, the following terms shall have the respective meanings specified or referred to in this Section 1:

"***Affiliate***" means, when used with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, controls or is controlled by or is under common control with the Person specified. For purposes of this definition, "control," when used with respect to any Person, means the power to direct the management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise. The terms "controlling" and "controlled" have meanings correlative to the foregoing.

"***Court Order***" means any judgment, order, award or decree of any foreign, federal, state, local or other court or administrative or regulatory body and any award in any arbitration proceeding.

"***Encumbrance***" means any lien (statutory or other), encumbrance, claim, charge, security interest, mortgage, deed of trust, pledge, hypothecation, assignment, conditional sale or other title retention agreement, preference, priority or other security agreement or preferential arrangement of any kind or nature, and any easement, encroachment, covenant, restriction, right of way, defect in title or other encumbrance of any kind.

"***Governmental Body***" means any foreign, federal, state, local or other government, governmental, statutory or administrative authority or regulatory body, self-regulatory organization or any court, tribunal or judicial or arbitral body.

"***Person***" means any individual, partnership, corporation, limited liability company, association, joint venture, joint-stock company, trust, unincorporated organization, Governmental Body or other entity.

"***Requirements of Law***" means any applicable foreign, federal, state and local laws, statutes, regulations, rules, codes, ordinances, Court Orders and requirements enacted, adopted, issued or promulgated by any Governmental Body or common law or any applicable consent decree or settlement agreement entered into with any Governmental Body.

"***SEC Reports***" means, collectively, all reports of the Company required to be filed by it under the Securities Act of 1933, as amended (the "***Securities Act***") and the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), including pursuant to Section 13(a) or 15(d) thereof, for the twelve months preceding the date hereof. The term "SEC Reports" shall not include any proxy statement (or amendment or supplement thereto) filed or prepared by the Company.

2. Purchases of Common Stock.

(a) Subscription. Subject to the terms and conditions hereof, the Investor hereby irrevocably subscribes for the Securities for the aggregate purchase price of US$2,017,500 (the "***Purchase Price***"), which is issuable and payable as described in Section 4. The Investor acknowledges that the Securities will be subject to restrictions on transfer as set forth in this Agreement.

(b) Compliance with NYSE American Rules. Notwithstanding anything in this Agreement to the contrary, unless permitted by the applicable rules and regulations of the NYSE American, the total number of shares of Common Stock that may be issued under this Agreement, shall not exceed the aggregate number of shares of Common Stock that the Company may issue without breaching the Company's obligations under the rules or regulations of the NYSE American (the number of shares that may be issued without violating such rules and regulations, the "***NYSE Cap***"). Notwithstanding the foregoing, such limitation shall not apply in the event that the Company obtains the approval of its stockholders as required by the applicable rules of the NYSE American for issuances of shares of Common Stock in excess of such amount the NYSE Cap, and shall also be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. The Company may, in its sole discretion, determine whether to obtain stockholder approval to issue more shares of Common Stock hereunder than is permitted by the NYSE Cap if such issuance would require stockholder approval under the rules or regulations of the NYSE American.

(c) Beneficial Ownership Limitation. The Company shall not issue, and an Investor shall not purchase, any shares of Common Stock under this Agreement, if such shares proposed to be issued and sold, when aggregated with all other shares of Common Stock then owned beneficially (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder) by the Investor and its affiliates would result in the beneficial ownership by the Investor and its affiliates of more than 33.3% of the then issued and outstanding shares of Common Stock.

3. Use of Proceeds. The Company intends to use the net proceeds received from the sale of the Securities or otherwise pursuant to this Agreement for general working capital purposes, including, without limitation, on product development and commercialization, development of intellectual property, purchases of inventory, sales and marketing, repayment of principal and interest on outstanding indebtedness, and other operating expenses.

4. Closing.

(a) Closing. The closing of the sale and purchase of the Securities (the "***Closing***") shall occur on such date and time as agreed upon by the parties hereto (the "***Closing Time***"); provided that the Closing Time shall occur no later than February 26, 2020. At the Closing Time, the Company shall deliver to the Investor the Securities against payment by the Investor of the Purchase Price for the Securities in accordance with Sections 4(b) and (c) below.

(b) Payment for Securities. At the Closing, the Investor shall pay to the Company an amount equal to the aggregate Purchase Price payable as full payment for the Securities issuable at the Closing via wire transfer of immediately available funds in accordance with the wiring instructions attached hereto as Appendix A or as otherwise designated by the Company, by check payable to the Company, or by any combination of such methods.

(c) Purchase Price. The per share purchase price with respect to the Investor shall be determined on the date the Investor signs this Agreement, and shall be equal to the greater of book or market value within the meaning of Section 713 of the NYSE American Company Guide.

5. Representations and Warranties of the Company. As of the date hereof and as of the Closing Time, the Company represents and warrants that:

(a) Organization. The Company is duly incorporated or formed and validly existing and in good standing under the law of its jurisdiction of incorporation or formation. The Company is duly qualified and in good standing as a foreign company in each other jurisdiction in which it owns or leases property or in which the conduct of its business requires it to be so qualified or licensed, except where the failure to be so qualified and in good standing would not, individually or in the aggregate, have or reasonably be expected to have a material adverse effect on the business, properties, financial condition, results of operations, or prospects of the Company (a "***Material Adverse Effect***").

(b) Authorization. The Company has all requisite power and authority to execute and deliver this Agreement and to perform its obligations hereunder in accordance with the terms hereof. The execution, delivery and performance of this Agreement by the Company have been duly authorized by all necessary corporate action. This Agreement has been duly executed and delivered by the Company, and this Agreement constitutes the legal, valid and binding obligation of the Company enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws relating to or affecting the enforcement of creditors' rights generally and by general equitable principles.

(c) No Violation; Consents and Approvals. The execution and delivery by the Company of this Agreement does not, and the consummation by the Company of any of the transactions contemplated hereby and compliance by the Company with the terms, conditions and provisions hereof (including the offer and sale of the Securities by the Company) will not conflict with, violate, result (with the giving of notice or passage of time or both) in a breach of the terms, conditions or provisions of, or constitute a default, an event of default or an event creating rights of acceleration, termination or cancellation or a loss of rights under, or result in the creation or imposition of any Encumbrance upon any of the assets or properties of the Company under (A) the certificate of incorporation or certificate of formation or the by-laws, each as applicable, of the Company, (B) any note, instrument, agreement, contract, mortgage, lease, license, franchise, guarantee, permit or other authorization, right, restriction or obligation to which the Company is a party or any of their respective assets or properties is subject or by which the Company is bound, (C) any Court Order to which the Company is a party or any of their respective assets or properties is subject or by which the Company is bound, or (D) any Requirements of Law applicable to the Company or any of their respective assets or properties.

(d) Capitalization. The Securities will be duly authorized, and when issued in accordance with this Agreement, (i) will be validly issued, fully paid and non-assessable and will be free and clear of any Encumbrances (other than, with respect to the Investor, any Encumbrances created by or through the Investor and restrictions on transfer imposed by the Securities Act, and applicable "blue sky" or other similar laws of the Investor's state of residence (referred to as the "***State Securities Laws***")) and the Investor will have good title thereto and (ii) will not have been issued in violation of any preemptive or subscription rights and will not result in the anti-dilution provisions of any security of the Company becoming applicable.

(e) Compliance with Laws. Except as may otherwise be described in the SEC Reports, the Company is in compliance with all laws and regulatory requirements to which it is subject, including U.S. sanctions laws and the Foreign Corrupt Practices Act, 15 U.S.C. §78 et seq., as it may be amended from time to time, except for such non-compliance that (A) could not reasonably be expected to have a Material Adverse Effect or (B) occurs as a result of any proceedings or investigations relating to any matter described in the SEC Reports.

(f) Private Offering. No form of general solicitation or general advertising was used by the Company, or to the knowledge of the Company, its authorized representatives, in connection with the offer or sale of the Securities to be issued under this Agreement. Assuming the accuracy of the representations and warranties of the Investor contained in Section 6, the issuance and sale of the Securities pursuant to this Agreement is exempt from the registration requirements of the Securities Act and applicable State Securities Laws, and neither the Company nor, to the knowledge of the Company, any authorized representative acting on its behalf has taken or will take any action hereafter that would cause the loss of such exemption. The Company agrees that neither it, nor, anyone authorized to act on its behalf, shall offer to sell the Securities to be issued under this Agreement or any other securities of the Company so as to require the registration of the Securities being offered hereby pursuant to the provisions of the Securities Act or any State Securities Laws, unless the offer and sale of the Securities to be issued under this Agreement or such other securities is so registered. Neither the Company nor to its knowledge any Affiliate of the Company, directly or indirectly through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of any security that is or will be integrated with the sale of the Securities in a manner that would require registration of the Securities under the Securities Act.

(g) No Restrictions on Common Stock. Except as described in the SEC Reports, (i) No Person has the right, contractual or otherwise, to cause the Company to issue or sell to it any shares of Common Stock or shares of any other capital stock or other equity interests of the Company and (ii) no Person has any purchase option, call option, preemptive rights, resale rights, subscription rights, rights of first refusal or other rights to purchase any shares of Common Stock or shares of any other capital stock of or other equity interests in the Company.

(h) Investment Company; Passive Foreign Investment Company. The Company is not and, after giving effect to the offer and sale of the Securities will not be an "investment company," required to register under the Investment Company Act of 1940, as amended. The Company does not believe that it is a "passive foreign investment company" as such term is defined in the Internal Revenue Code of 1986, as amended from time to time, and the regulations promulgated thereunder (the "***Code***").

(i) Compliance with SEC Filings.

(i) The Company has filed all SEC Reports required to be filed by it with the U.S. Securities and Exchange Commission (the "***SEC***") for the twelve months preceding the date hereof. As of their respective dates or, if amended, as of the date of such amendment, the SEC Reports complied in all material respects with the requirements of the Securities Act, Exchange Act and the Sarbanes-Oxley Act of 2002 and the applicable rules and regulations promulgated thereunder, and none of the SEC Reports included any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act.

(ii) The audited consolidated financial statements and unaudited consolidated financial statements (including all related notes and schedules) of the Company included in the SEC Reports complied as to form in all material respects with the rules and regulations of the SEC then in effect, fairly present in all material respects the consolidated financial position of the Company and its consolidated subsidiaries, as of the respective dates thereof, and the consolidated results of their operations and their consolidated cash flows for the respective periods then ended (subject, in the case of the unaudited statements, to normal recurring year-end audit adjustments that were not or are not expected to be, individually or in the aggregate, materially adverse to the Company), and were prepared in accordance with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis during the periods involved, except as otherwise disclosed in the Company SEC Documents.

(j) Registration and Listing of Common Stock. The class of Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act. The Common Stock is listed on the NYSE American, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the NYSE American. As of the date of this Agreement, except as disclosed in the SEC Reports, the Company has not received any notification that, and has no knowledge that, the SEC or the NYSE American is contemplating terminating such registration or listing.

6. Representations and Warranties of the Investor. As an inducement to the Company to enter into this Agreement and to consummate the transactions contemplated hereby, the Investor represents and warrants as of the date hereof and as of Closing Time, as follows:

(a) Authorization. Investor has full capacity to execute and deliver this Agreement and to perform its obligations hereunder in accordance with the terms hereof. This Agreement has been, and at or prior to the Closing will have been, duly executed and delivered by the Investor, and constitutes the legal, valid and binding obligation of the Investor, enforceable against the Investor in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws relating to or affecting the enforcement of creditors' rights generally and by general equitable principles.

(b) No Consents Required. No approval, authorization, consent or order of or filing with any federal, state, local or foreign government or regulatory commission, board, body, authority or agency, or of or with any self-regulatory organization, or other non-governmental regulatory authority (including any national securities exchange), is required in connection with the execution, delivery and performance of this Agreement by Investor or the consummation by the Investor of the transactions contemplated hereby, except for such approvals, authorizations, consents, orders or filings that have been obtained or made and are in full force and effect.

(c) No Violation. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby will not conflict with, result in any breach or violation of or constitute a default under (or constitute any event which with notice, lapse of time or both would result in any breach or violation of or constitute a default under or give the holder of any indebtedness (or a Person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under) (or result in the termination of, or in the creation or imposition of a lien, charge or Encumbrance on any property or assets of Investor pursuant to) (i) any indenture, mortgage, deed of trust, bank loan or credit agreement or other evidence of indebtedness, or any license, lease, contract or other agreement or instrument to which the Investor is a party or by which the Investor or any of its properties may be bound or affected, (ii) any federal, state, local or foreign law, regulation or rule, (iii) any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including any national securities exchange) or (iv) any Court Order applicable to the Investor or any of its properties, except in the case of the foregoing clauses (i), (ii), (iii) and (iv) as would not individually or in the aggregate, materially and adversely affect the Investor's ability to perform its obligations under this Agreement or consummate the transactions contemplated herein on a timely basis.

(d) Reserved.

(e) Accredited Investor and Qualified Institutional Buyer.

(i) Investor is acquiring the Securities to be issued under this Agreement to Investor for its own account, not as nominee or agent, with the present intention of holding such securities for purposes of investment, and not with the view to the public resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the U.S. federal securities laws or any applicable State Securities Laws. Investor is purchasing and holding any purchased Securities for its own account and is not party to any co-investment, joint venture, partnership or other understandings or arrangements with any other party relating to the Securities or any other transactions contemplated hereunder.

(ii) Investor is an "accredited investor" as such term is defined in Rule 501(a) of Regulation D under the Securities Act or a "qualified institutional buyer" within the meaning of Rule 144A under the Securities Act and a "qualified purchaser" as defined in Section 2(a)(51)(A) of the Investment Company Act of 1940, as amended.

(iii) Investor acknowledges that it has completed the Investor Questionnaire contained inAppendix B and that the information contained therein is complete and accurate as of the date thereof and is hereby affirmed as of the Closing Time. Any information that has been furnished or that will be furnished by Investor to evidence its status as an accredited investor is accurate and complete, and does not contain any misrepresentation or material omission.

(iv) Investor has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Company, and has so evaluated the merits and risks of such investment, and understands that it may be required to bear the risks thereof. Investor has previously invested in securities similar to the Securities and fully understands the limitations on transfer and restrictions on sales of the Securities. Investor represents that it is able to bear the economic risk of its investment in the Securities and is able to afford the complete loss of any such investment.

(v) Investor has conducted its own independent evaluation, made its own analysis and consulted with advisors as it has deemed necessary, prudent, or advisable in order for the Investor to make its own determination and decision to enter into the transactions contemplated by this Agreement and to execute and deliver this Agreement.

(vi) Investor has reviewed the SEC Reports (including all disclosures related to the potential delisting of the Common Stock from the NYSE American exchange if Navidea does not regain compliance with the continued listing requirements of the NYSE American exchange by February 14, 2020 (the "***Potential Delisting***")) and is familiar with the business and financial condition and operations of the Company. Investor has had an opportunity to discuss the Potential Delisting and the terms and conditions of the offering of the Securities with the Company's management to enable it to evaluate the transactions contemplated by this Agreement and to make an informed investment decision concerning the Securities, and Investor has had the opportunity to obtain and review information reasonably requested by the Investor.

(vii) Investor is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or, to the Investor's knowledge, any other general solicitation or general advertisement. Neither Investor nor its Affiliates or any person acting on its or any of their behalf has engaged, or will engage, in any form of general solicitation or general advertising (within the meaning of Rule 502(c) under the Securities Act) in connection with the offering of the Securities.

(viii) Investor has sufficient cash on hand or other immediately available funds to pay the aggregate Purchase Prices and otherwise satisfy its obligations in connection with this Agreement and the transactions contemplated hereby.

(ix) Investor is not subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) through (viii) under the Securities Act, except for Disqualification Events covered by Rule 506(d)(2)(ii) or (iii) under the Securities Act and disclosed in writing in reasonable detail to the Company.

(f) No Broker's Fees. No brokerage or finder's fees or commissions are or will be payable by the Investor to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the issuance of the Securities, and Investor has not taken any action that could cause the Company to be liable for any such fees or commissions.

(g) Advisors. Investor acknowledges that, prior to entering into this Agreement, it was advised by Persons deemed appropriate by Investor concerning this Agreement and the transactions contemplated hereunder and conducted its own due diligence investigation (including with respect to the Potential Delisting) and made its own investment decision with respect to this Agreement, the transactions contemplated hereunder and the purchase of the Securities.

(h) Arm's Length Transaction. Investor is acting solely in the capacity of an arm's length contractual counterparty to the Company with respect to the transactions contemplated hereby. Additionally, without derogating from or limiting the representations and warranties of the Company, Investor (i) is not relying on the Company for any legal, tax, investment, accounting or regulatory advice; (ii) has consulted with its own advisors concerning such matters; and (iii) shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby.

(i) No Further Reliance. Investor acknowledges that it is not relying upon any representation or warranty made by the Company that is not set forth in this Agreement or in the Company's public filings. Investor confirms that the Company has not (i) given any guarantee or representation as to the potential success, return, effect or benefit (either legal, regulatory, tax, financial, accounting or otherwise) of an investment in the Securities; (ii) made any representation to the Investor regarding the legality of an investment in the Securities under applicable legal investment or similar laws or regulations, except as set forth herein; or (iii) the likelihood or ability of the Company to regain compliance with the continued listing requirements of the NYSE American exchange or continue trading on a national securities exchange. Investor confirms that (A) it has conducted a review and analysis of the business, assets, condition, operations and prospects of the Company, and the terms of the Securities, and has access to such financial and other information regarding the Company, in each case that the Investor considers sufficient for purposes of the purchase of the Securities; (B) at a reasonable time prior to its purchase of the Securities, it had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Securities and to obtain additional information necessary to verify any information furnished to the Investor or to which the Investor had access; and (C) it has not received any offering memorandum or offering document in connection with the offering of the Securities.

(j) Private Placement. Investor understands and acknowledges that:

(i) The Securities that it is acquiring under this Agreement are being sold pursuant to an exemption from registration under the Securities Act. The Company may require additional information from Investor in respect of matters under such exemption from registration under the Securities Act, and the Investor shall provide such reasonably requested information to the Company on a timely basis so that the Company may comply with the requirements thereunder.

(ii) Its representations and warranties contained herein (including the accompanying Investor Questionnaire) are being relied upon by the Company as a basis for such exemption under the Securities Act and under the State Securities Laws. Investor further understands that, unless it notifies the Company in writing to the contrary at or before the Closing Time, the Investor's representations and warranties contained in this Agreement will be deemed to have been automatically (and without any further action of the Investor) reaffirmed and confirmed as of the Closing Time, taking into account all information received by the Investor. Investor agrees to hold the Company and its directors, officers, employees, affiliates, controlling persons, and agents harmless, and to indemnify them against any and all liabilities, costs, and expenses incurred by them as a result of (A) any misrepresentation made by the Investor contained in this Agreement or the accompanying Investor Questionnaire; (B) any sale or distribution by the Investor in violation of the Securities Act or any applicable state securities or "blue sky" laws; or (C) any untrue statement of a material fact made by the Investor and contained herein.

(iii) No U.S. state or federal agency or any other securities regulator of any state or country has passed upon or made any recommendation or endorsements of the merits or risks of an investment in the Securities or made any finding or determination as to the fairness of the terms of the offering of the Securities or any recommendation or endorsement thereof.

(iv) The Securities are "restricted securities" under applicable federal securities laws and that the Securities Act and the rules of the U.S. Securities and Exchange Commission (the "***SEC***") provide in substance that Investor may dispose of the Securities only pursuant to an effective registration statement under the Securities Act or an exemption therefrom. Investor understands that under the SEC's rules, the Investor may dispose of the Securities principally only in "private placements" or other transactions that are exempt from registration under the Securities Act, in which event the transferee may acquire "restricted securities" subject to the same limitations as in the hands of the Investor. Consequently, Investor understands that the Investor must bear the economic risks of the investment in the Securities for an indefinite period of time. Investor will not sell, assign, pledge, give, transfer or otherwise dispose of the Securities or any interest therein, or make any offer or attempt to do any of the foregoing, except pursuant to a registration of the Securities under the Securities Act and all applicable State Securities Laws, or in a transaction which is exempt from the registration provisions of the Securities Act and all applicable State Securities Laws. Investor understands that that the recordation of the Securities in book-entry form will include a legend substantially in the form indicated in Section 7 (which Investor has read and understands), and that the Company and its Affiliates shall not be required to give effect to any purported transfer of such Securities except upon compliance with the foregoing restrictions.

(k) No ERISA Plans. Either (a) Investor is not purchasing or holding Securities (or any interest in Securities) with the assets of (i) an employee benefit plan that is subject to Title I of ERISA, (ii) a plan, individual retirement account or other arrangement that is subject to Section 4975 of the Code, (iii) an entity whose underlying assets are considered to include "plan assets" of any of the foregoing by reason of such plan's, account's or arrangement's investment in such entity, or (iv) a governmental, church, non-U.S. or other plan that is subject to any similar laws; or (b) the purchase and holding of such Securities by the Investor, throughout the period that it holds such Securities, and the disposition of such Securities or an interest therein will not constitute (x) a non-exempt prohibited transaction under Section 406 of ERISA or Section 4975 of the Code, (y) a breach of fiduciary duty under ERISA or (z) a similar violation under any applicable similar laws.

7. Additional Agreements.

(a) Short Selling Acknowledgement and Agreement. Investor understands and acknowledges that the SEC currently takes the position that coverage of Short Sales of securities "against the box" prior to the effective date of a registration statement is a violation of Section 5 of the Securities Act and of Securities Act Compliance Disclosure Interpretation 239.10. Investor agrees that it will abide by such interpretation and will not engage in any Short Sales that result in the disposition of the Securities acquired hereunder by the Investor until such time as a resale registration statement is declared or deemed effective by the SEC or such Securities are no longer subject to any restrictions on resale. "***Short Sales***" means all "short sales" as defined in Rule 200 promulgated under Regulation SHO under the Exchange Act, whether or not against the box, and forward sale contracts, options, puts, calls, short sales, "put equivalent positions" (as defined in Rule 16a-1(h) under the Exchange Act) and similar arrangements, and sales and other transactions through non-U.S. broker dealers or foreign regulated brokers.

(b) Legend. The book-entry account maintained by the transfer agent evidencing ownership of the Securities sold pursuant to this Agreement will bear the following restrictive legend in substantially the following form:

> "THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR THE SECURITIES LAWS OF ANY STATE. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT (1) OUTSIDE THE UNITED STATES IN AN OFFSHORE TRANSACTION IN COMPLIANCE WITH RULE 903 OR RULE 904 UNDER THE SECURITIES ACT, PURSUANT TO THE EXEMPTION FROM REGISTRATION PROVIDED BY RULE 144 UNDER THE SECURITIES ACT (IF AVAILABLE), OR ANOTHER EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT (AND BASED UPON AN OPINION OF COUNSEL IF THE ISSUER SO REQUESTS), OR (2) PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT."

(c) Intentionally Omitted.

(d) Blue Sky. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the offer and sale of the Securities to the Investor pursuant to this Agreement under applicable State Securities Laws (or to obtain an exemption from such qualification), and shall provide evidence of any such action so taken to the Investor. The Company shall timely make all filings and reports relating to the offer and sale of the Securities issued hereunder required under applicable State Securities Laws. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section 7(d).

(e) Rule 144 Reporting. For so long as the Investor holds Securities that are not freely transferable without restriction under the Securities Act (including the current public information requirement under Rule 144 of the Securities Act), the Company shall (i) make and keep public information available, as those terms are understood and defined in Rule 144 of Securities Act; and (ii) file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act.

(f) Registration Rights Agreement. The Company shall enter into a Registration Rights Agreement between the Company and the Investor, in substantially the form attached hereto as Appendix C ("***Registration Rights Agreement***").

8. Conditions to Obligations of the Company. The obligation of the Company to sell and issue the Securities to the Investor at the Closing Time is subject to the fulfillment on or before the Closing Time of the following conditions, any of which may be waived (in whole or in part) by the Company in its sole discretion:

(a) No Injunction. As of the Closing Time, no Governmental Body nor any other Person shall have issued an order, injunction, judgment, decree, ruling or assessment which shall then be in effect restraining or prohibiting the completion of the transactions contemplated by this Agreement, nor to the Company's knowledge, shall any such order, injunction, judgment, decree, ruling or assessment be threatened or pending.

(b) Purchase Price Paid. The Investor shall have paid the aggregate Purchase Price to the Company, pursuant to the requirements of this Agreement.

(c) Covenants and Agreements. The Investor shall have performed and complied with the covenants and agreements required to be performed or complied with by the Investor hereunder on or prior to the Closing Time.

(d) Representations and Warranties. The representations and the warranties of the Investor contained in this Agreement shall be true and correct in all material respects as of the Closing Time, with the same effect as though such representations and warranties had been made on and as of such date.

9. Conditions to Obligations of the Investor. The irrevocable obligation of the Investor to pay the Company the aggregate Purchase Price in respect of the Securities to be issued under this Agreement to the Investor is subject solely to the fulfillment of, or, to the extent permitted by law, waiver by, the Investor prior to the Closing Time, as the case may be, of each of the following conditions:

(a) Covenants and Agreements. The Company shall have performed and complied in all material respects with the covenants and agreements required to be performed or complied with by it hereunder on or prior to the Closing Time, as applicable.

(b) Representations and Warranties. The representations and the warranties of the Company contained in this Agreement shall be true and correct in all material respects as of the Closing Time, except with respect to provisions including the terms "material," "Material Adverse Effect" or words of similar import and except with respect to materiality, as reflected under GAAP, and with respect to which such representations and warranties made as of the applicable date, such representations and warranties shall be true and correct only as of such date.

10. Miscellaneous.

(a) Survival of Obligations. All representations, warranties, covenants, agreements and obligations contained in this Agreement shall survive (i) the acceptance of the Subscriptions by the Company and the Closing and (ii) the death or disability of the Investor.

(b) Notices. All notices or other communications required or permitted hereunder shall be in writing and shall be deemed given or delivered (i) when delivered personally, (ii) when delivered by electronic mail (so long as notification of a failure to deliver such electronic mail is not received by the sending party), (iii) if transmitted by electronic mail when confirmation of transmission is received by the sending party, (iv) if sent by registered or certified mail, postage prepaid, return receipt requested, on the third business day after mailing or (v) if sent by reputable overnight courier when received; and shall be addressed to the Investor or to the Company as follows:

If to the Company:	Navidea Biopharmaceuticals, Inc. 4995 Bradenton Avenue Suite 240 Dublin, Ohio 43017 Attention: Jed A. Latkin, Chief Executive Officer Email: jlatkin@navidea.com
with a copy to:	Thompson Hine LLP 335 Madison Avenue 12th Floor New York, New York 10017-4611 Attention: Faith L. Charles Email: Faith.Charles@ThompsonHine.com
If to Investor:	5251 DTC Parkway, Suite 285 Greenwood Village, CO 80111 Email: jks3@cheqnet.net
with a copy to:	Winstead PC 401 Congress Ave. Suite 2100 Austin, Texas 78701-3619 Attention: James G. Ruiz Email: jruiz@winstead.com

Any party hereto may, from time to time, change its address, e-mail address or other information for the purpose of notices to that party by giving notice specifying such change to the other party hereto.

(c) Execution in Counterparts; Effectiveness. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, and shall become binding when one or more counterparts have been signed by and delivered to each of the parties hereto.

(d) Amendments. This Agreement shall not be amended, modified or supplemented except by a written instrument signed by the parties hereto.

(e) Expenses. The Investor shall be responsible for its own costs and expenses in connection herewith, including the fees and expenses, if any, of its advisors and its counsel.

(f) Waiver. Any term or provision of this Agreement may be waived, or the time for its performance may be extended, by the party entitled to the benefit thereof. Any such waiver shall be validly and sufficiently authorized for the purposes of this Agreement if, as to any party, it is in writing signed by an authorized representative of such party. The failure or delay of any party to enforce at any time any provision of this Agreement shall not be construed to be a waiver of such provision, nor in any way to affect the validity of this Agreement or any part hereof or the right of any party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach.

(g) Severability. Wherever possible, each provision hereof shall be interpreted in such manner as to be effective and valid under applicable law, but in case any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such provision shall be ineffective to the extent, but only to the extent, of such invalidity, illegality or unenforceability without invalidating the remainder of such invalid, illegal or unenforceable provision or provisions or any other provisions hereof, unless such a construction would be unreasonable.

(h) Assignment; Successors and Assigns. Neither this Agreement nor any of the rights and obligations of any party hereunder may be assigned, delegated or otherwise transferred by either party hereto without the prior written consent of the other party hereto. No such assignment, delegation or other transfer shall relieve the assignor of any of its obligations or liabilities hereunder. This Agreement shall be binding upon and shall inure to the benefit of the parties and their respective successors and permitted assigns.

(i) No Third Party Beneficiaries. Nothing in this Agreement, express or implied, is intended or shall be construed to confer upon any third Person, other than the parties and their respective successors and assigns permitted by Section 10(h), any right, remedy or claim under or by reason of this Agreement.

(j) Governing Law. This Agreement shall be governed by and construed in accordance with the substantive laws of the State of New York without regard to its conflict of laws principles.

(k) Submission to Jurisdiction. Each of the parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the non-exclusive jurisdiction of the state district courts of the State of New York and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Agreement, or for recognition or enforcement of any judgment, and each of the parties hereto hereby irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in New York or, to the extent permitted by law, in such Federal court. Each of the parties hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Nothing in this Agreement shall affect any right that the Investor may otherwise have to bring any action or proceeding relating to this Agreement against the Company and its subsidiaries or their respective properties in the courts of any jurisdiction or any right that the Company may otherwise have to bring any action or proceeding relating to this Agreement against the Investor or its properties in the courts of any jurisdiction. Each party hereto irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of venue of any such proceeding brought in such a court referred to in the first sentence of this Section 10(k) and any claim that any such proceeding brought in such a court has been brought in an inconvenient forum.

(l) Waiver of Jury Trial. EACH PARTY HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY(WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, TO IT THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

(m) Public Announcements. The Investor shall not make any public announcements or otherwise communicate with the news media with respect to this Agreement or the transactions contemplated hereby without the prior written consent of the Company. Notwithstanding the forgoing, the Investor may make or cause to be made any press release or similar public announcement or communication as may be required to comply with (i) the requirements of applicable law, including the Exchange Act or (ii) its disclosure obligations or practices with respect to its investors; *provided* that prior to making any such disclosure under this clause (ii), the Investor shall provide a copy of such proposed disclosure to the Company and shall only publicly make such disclosure with the consent of the Company, which consent shall not be unreasonably withheld or delayed, if the Company has not previously made a public announcement of the transactions contemplated hereby.

(n) Entire Agreement. This Agreement and the Appendices, and the documents delivered pursuant hereto and thereto constitute the entire agreement and understanding among the parties with respect to the subject matter contained herein or therein, and supersede any and all prior agreements, negotiations, discussions, understandings, term sheets or letters of intent between or among of the parties with respect to such subject matter.

(o) Interpretation.

In this Agreement, unless the context clearly indicates otherwise:

(i) words used in the singular include the plural and words in the plural include the singular;

(ii) reference to any gender includes the other gender;

(iii) the word “including” (and with correlative meaning “include”) means “including but not limited to” or “including without limitation”;

(iv) reference to any Section or Appendix means such Section of, or such Appendix to, this Agreement, as the case may be, and reference in any Section or definition to any clause means such clause of such Section or definition;

(v) the words “herein,” “hereunder,” “hereof,” “hereto” and words of similar import shall be deemed references to this Agreement as a whole and not to any particular Section or other provision hereof;

(vi) reference to any agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof and by this Agreement;

(vii) reference to any law (including statutes and ordinances) means such law (including all rules and regulations promulgated thereunder) as amended, modified, codified or reenacted, in whole or in part, and in effect at the time of determining compliance or applicability;

(viii) relative to the determination of any period of time, "from" means "from and including," "to" means "to but excluding" and "through" means "through and including"; and

(ix) the titles and headings of Sections contained in this Agreement have been inserted for convenience of reference only and shall not be deemed to be a part of or to affect the meaning or interpretation of this Agreement.

(p) This Agreement was negotiated by the parties with the benefit of legal representation, and no rule of construction or interpretation otherwise requiring this Agreement to be construed or interpreted against any party shall apply to any construction or interpretation hereof. Subject to Section 10(g), this Agreement shall be interpreted and construed to the maximum extent possible so as to uphold the enforceability of each of the terms and provisions hereof.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the undersigned has executed this Agreement as of the first date written above.

INVESTOR:

/s/ John K. Scott, Jr.
JOHN K. SCOTT, JR.

[*Signature Page to Stock Purchase Agreement*]

IN WITNESS WHEREOF, the undersigned has executed this Agreement as of the first date written above.

NAVIDEA BIOPHARMACEUTICALS, INC.

By: /s/ Jed A. Latkin
Name: Jed A. Latkin
Title: Chief Executive Officer, Chief Financial Officer and Chief Operating Officer

[*Signature Page to Stock Purchase Agreement*]

Exhibit 21.1

Subsidiaries of Navidea Biopharmaceuticals, Inc.

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

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Navidea Biopharmaceuticals, Inc. on Form S-3 (File Nos. 333-235762, 333-222092, 333-195806, 333-193330, 333-184173, 333-173752, 333-168485, 333-76151, and 333-15989) and Form S-8 (Nos. 333-228960, 333-217814, 33-81410, 333-119219, 333-130636, 333-130640, 333-153110, 333-158323, 333-183317, 333-05143, 333-21053, and 333-198716) of our report, which includes an explanatory paragraph as to the company's ability to continue as a going concern, dated March 18, 2020, with respect to our audits of the consolidated financial statements of Navidea Biopharmaceuticals, Inc. as of December 31, 2019 and 2018 and for the years then ended, which report is included in this Annual Report on Form 10-K of Navidea Biopharmaceuticals, Inc. for the year ended December 31, 2019. Our report on the consolidated financial statements refers to the change in the method of accounting for leases effective January 1, 2019.

/s/ Marcum LLP

Marcum LLP
New Haven, Connecticut
March 18, 2020

Marcum LLP ▪ 555 Long Wharf Drive ▪ 12th Floor ▪ New Haven, Connecticut 06511 ▪ Phone 203.781.9600 ▪ Fax 203.781.9601 ▪ www.marcumllp.com

Exhibit 24.1

POWER OF ATTORNEY

Each of the undersigned officers and directors of Navidea Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby constitute and appoint Jed A. Latkin as his or her agent and lawful attorney-in-fact, in his or her name and on his or her behalf, and in any and all capacities stated below:

- To sign and file with the United States Securities and Exchange Commission the Annual Report of the Company on Form 10-K (the "Annual Report") for the fiscal year ended December 31, 2019, and any amendments or supplements to such Annual Report; and

- To execute and deliver any instruments, certificates or other documents which they shall deem necessary or proper in connection with the filing of such Annual Report, and generally to act for and in the name of the undersigned with respect to such filing as fully as could the undersigned if then personally present and acting.

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

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

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

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

IN WITNESS WHEREOF, the undersigned have executed this Power of Attorney effective as of March 18, 2020.

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

Exhibit 31.1

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

I, Jed A. Latkin, certify that:

1. I have reviewed this annual report on Form 10-K of Navidea Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 18, 2020

/s/ Jed A. Latkin
Jed A. Latkin
Chief Executive Officer, Chief Operating Officer, and
Chief Financial Officer

Exhibit 32.1

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

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

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

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

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

March 18, 2020

/s/ Jed A. Latkin
Jed A. Latkin
Chief Executive Officer, Chief Operating Officer, and
Chief Financial Officer