# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K**

(Mark One)  Mark One)  ANNUAL REPORT PURSUANT TO SECTION 1.	3 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal	year ended December 31, 2017
	or
☐ TRANSITION REPORT PURSUANT TO SECTION	ON 13 OR 15(d) OF THE EXCHANGE ACT
For the transition	period from to to
	sion file number <u>001-35076</u>
NAVIDEA BIOPH	ARMACEUTICALS, INC.
(Exact name of re	egistrant as specified in its charter)
Delaware	31-1080091
(State or other jurisdiction of incorporation or organiz	ation) (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 n	umber, including area code <u>(614) 793-7500</u>
Securities registered	pursuant to Section 12(b) of the Act:
Common Stock, par value \$.001 per share	NYSE American
(Title of Class)	(Name of Each Exchange on Which Registered)
Securities registered pursuant to Section 12(g) of the Act: N	one
Indicate by check mark if the registrant is a well-known seas	soned issuer, as defined in Rule 405 of the Securities Act. Yes $\square$ No $\boxtimes$
Indicate by check mark if the registrant is not required to file	e reports pursuant to Section 13 or Section 15(d) of the Act. Yes $\square$ No $\boxtimes$
	Il reports required to be filed by Section 13 or 15(d) of the Securities or such shorter period that the registrant was required to file such reports), and 90 days. Yes $\boxtimes$ No $\square$
	electronically and posted on its corporate Web site, if any, every Interactive ule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 quired to submit and post such files). Yes $\boxtimes$ No $\square$
	suant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not gistrant's knowledge, in definitive proxy or information statements by amendment to this Form 10-K.
	elerated filer, an accelerated filer, a non-accelerated filer, smaller reporting ons of "large accelerated filer," "accelerated filer," "smaller reporting of the Exchange Act.
Large accelerated filer □ Non-accelerated filer □	Accelerated filer (Do not check if a smaller reporting company) Smaller reporting company  Emerging growth company
	he registrant has elected not to use the extended transition period for ndards provided pursuant to Section 13(a) of the Exchange Act. $\Box$
Indicate by check mark whether the registrant is a shell com	pany (as defined in Rule 12-b-2 of the Act.) Yes □ No ⊠
The aggregate market value of shares of common stock held	by non-affiliates of the registrant on June 30, 2017 was \$78,564,174.

The number of shares of common stock outstanding on March 1, 2018 was 162,783,979.

## DOCUMENTS INCORPORATED BY REFERENCE

None.		

The Private Securities Litigation Reform Act of 1995 (the "PSLRA") provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this document which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, the ability to obtain, and timing of, regulatory approvals of the Company's products, the timing and anticipated results of commercialization efforts, and anticipated markets for the Company's products, are forward-looking statements within the meaning of the PSLRA. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, material weaknesses in our internal control over financial reporting and our ability to maintain effective controls of financial reporting in the future, the Company's continuing operating losses, uncertainty of market acceptance, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on earnouts, royalties and grant revenue, limited product line and distribution channels, competition, risks of development of new products, and other risks set forth below under Item 1A, "Risk Factors." The Company undertakes no obligation to publicly update or revise any forward-looking statements.

#### PART I

#### Item 1. Business

#### **Development of the Business**

Navidea Biopharmaceuticals, Inc. ("Navidea," the "Company," or "we"), a Delaware corporation (NYSE 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<sup>TM</sup> platform to enhance patient care by identifying the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and targeted treatment.

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc99m tilmanocept, the first product developed and commercialized by Navidea based on the platform.

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

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

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

In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately \$80.6 million after adjustments based on inventory being transferred and an advance of \$3.0 million of guaranteed earnout payments as part of the CRG settlement (described below in Item 3 – Legal Proceedings), (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to Capital Royalty Partners II L.P. ("CRG") as part of the Deposit Amount paid to CRG (described below in Item 3 – Legal Proceedings).

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

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

Other than 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, our R-NAV joint venture (terminated on May 31, 2016), NAV4694 and NAV5001 (license terminated in April 2015), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by Macrophage Therapeutics, Inc. See Note 21 to the consolidated financial statements for more information about our business segments.

## **Our History**

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

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

From our inception through August 2011, we manufactured a line of gamma radiation detection medical devices called the neoprobe <sup>®</sup> GDS system (the "GDS Business"). We sold the GDS Business to Devicor Medical Products, Inc. ("Devicor") in August 2011. In exchange for the assets of the GDS Business, Devicor made net cash payments to us totaling \$30.3 million, assumed certain liabilities of the Company associated with the GDS Business, and agreed to make royalty payments to us of up to an aggregate maximum amount of \$20.0 million based on the net revenue attributable to the GDS Business through 2017. Based on the 2015 GDS Business revenue, we earned royalty payments of \$1.2 million. We did not earn any such royalty payments prior to 2015 or in 2016 and 2017.

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

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

## **Our Technology and Product Candidates**

Our primary development efforts over the last 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.

The flexible and versatile Manocept acts as a platform molecular engine for the design of targeted imaging molecules 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. Active clinical diagnostic programs in several diseases (discussed below) representing specific macrophage activation states are ongoing.

Cardiovascular Disease ("CV") – A nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc99m tilmanocept product dosed subcutaneously was completed (ClinicalTrials.gov NCT02542371). The results of this study were presented at two major international meetings (Conference on Retroviruses and Opportunistic Infections ("CROI") and Society of Nuclear Medicine and Molecular Imaging ("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 begun a second Phase1/2 study in cooperation with Massachusetts General Hospital. This study expands the initial investigation to the assessment of not only aortic plaque but also carotid and coronary arteries. In addition, we have applied for follow-on NIH/NHLBI support to fund additional clinical studies. These studies are currently under development and design for Phase 2 trials.

Rheumatoid Arthritis ("RA") – Two Tc99m tilmanocept dose escalation studies in RA have been initiated. The first study, now complete (ClinicalTrials.gov NCT02683421), included 18 subjects (nine with active disease and nine healthy subjects) dosed subcutaneously with 50 and 200  $\mu$ g/2mCi Tc99m tilmanocept. The results of this study were presented at three international meetings, including Biotechnology Innovation Organization ("BIO"), SNMMI, and The American College of Rheumatology ("ACR"), 2017. This study is submitted for peer review publication. In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have completed a study involving intravenous ("IV") dosing of Tc99m tilmanocept (ClinicalTrials.gov NCT02865434). In conjunction with this study, we have completed pharmacokinetic ("PK") and pharmacodynamics ("PD") phases in human subjects as well. The majority of the studies have been supported through a Small Business Innovation Research ("SBIR") grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1). We anticipate a presentation of the results at the 2018 SNMMI meeting and full published results thereafter.

Kaposi's Sarcoma ("KS") – Although we initiated and completed a study of KS in 2015 (ClinicalTrials.gov NCT022201420), we received additional funding from the National Institutes of Health ("NIH") in 2016 to continue both diagnostic and therapeutic 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). Additionally, we received funding to support the therapeutic initiative for KS employing a select form of the MT-1001.3 agent under current evaluation. The Company has already completed a portion of the Phase 1 SBIR portion of this award (NIH/NCI 1 R44 CA206788-01) and will complete Phase 2 of the award with FDA investigational new drug ("IND") filing.

Colorectal Cancer ("CRC") and Synchronous Liver Metastases – During the first quarter of 2017, we initiated an imaging study in subjects with CRC and liver metastases via IV administration of Tc99m tilmanocept. This study has results but will continue to enroll subjects (up to 12 subjects with dose modification; this study may also be expanded depending on NIH/NCI funding). This study is supported through a SBIR grant (NIH/NCI 1 R44 CA1962783-01A1; ClinicalTrials.gov NCT03029988).

Nonalcoholic Steatosis Hepatitis ("NASH") – Navidea has initiated a study in the imaging of NASH. This study (ClinicalTrials.gov NCT03332940) is designed to enroll 12 subjects with IV administration of Tc99m tilmanocept and an imaging comparator, and includes dose escalation modification for Tc99m tilmanocept. This study is ongoing and has results which will be reported later in the year.

Based on performance in these very large market opportunities, the Company anticipates continued investment in these programs, including initiating studies designed to obtain new approvals for the Tc99m tilmanocept product.

The Company has completed further 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. Our efforts in this area were further supported by the 2015 formation of MT, a majority-owned subsidiary that was formed specifically to explore therapeutic applications for the Manocept platform. Results of these preclinical efforts will be published later this year pending the conclusion of intellectual property applications.

MT has been set up to pursue the therapeutic drug delivery model. This model enables the Company to leverage its technology over many potential disease applications and with multiple partners simultaneously without significant capital outlays. To date, the Company has developed two lead families of therapeutic products. The MT-1000 class is designed to deplete activated macrophages via apoptosis. The MT-2000 class is designed to modulate activated macrophages from a classically activated phenotype to the alternatively activated phenotype. Both families have been tested in a number of disease models in rodents.

We continue to seek to partner or out-license NAV4694. On October 26, 2017, the Company executed a letter of intent with Hainan Sinotau Pharmaceutical Co., Ltd. ("Sinotau") and Cerveau Technologies, Inc. ("Cerveau"), outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, People's Republic of China ("China") and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims. See Item 3 – Legal Proceedings.

The NAV5001 sublicense was terminated in April 2015.

## Manocept Platform - Diagnostics and Therapeutics Background

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. Activated macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. This flexible and versatile platform serves as an engine for purpose-built molecules that may significantly impact patient care by providing enhanced diagnostic accuracy, clinical decision-making, and target-specific treatment. This disease-targeted drug platform provides the capability to utilize a breadth of diagnostic modalities, including SPECT, PET, gamma-scan (both imaging and topical), intra-operative and/or optical-fluorescence detection, as well as delivery of therapeutic compounds that target macrophages, and their role in a variety of immune- and inflammation-based disorders. The FDA-approved sentinel node/lymphatic mapping agent, Tc99m tilmanocept, is representative of the ability to successfully exploit this mechanism to develop powerful new products and to expand this technology application into commercially advantageous markets.

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 perhaps 700 million worldwide, making macrophage-mediated diseases an area of remarkable clinical importance. There are many recognized disorders having macrophage involvement, including RA, atherosclerosis/vulnerable plaque, nonalcoholic steatohepatitis ("NASH"), inflammatory bowel disease, systemic lupus erythematosus, KS, and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, CNS diseases, and inflammation.

In July 2014, the Company completed a license agreement with UCSD for the exclusive world-wide rights in all diagnostic and therapeutic uses of tilmanocept, except for the use of Tc99m tilmanocept in Canada, Mexico and the United States, which rights have been licensed directly to Cardinal Health 414 by UCSD in connection with the Asset Sale. The license agreement is effective until the third anniversary of the expiration date of the longest-lived underlying patent. Under the terms of the license agreement, UCSD has granted Navidea the exclusive rights to make, use, sell, offer for sale and import licensed products for all diagnostic and therapeutic uses as defined in the agreement and to practice the defined licensed methods during the term of the agreement. Navidea may also sublicense the patent rights, subject to certain sublicense terms as defined in the agreement. As consideration for the license rights, Navidea agreed to pay UCSD a license issue fee of \$25,000 and license maintenance fees of \$25,000 per year. We also agreed to make payments to UCSD upon successfully reaching certain clinical, regulatory and cumulative sales milestones, and a royalty on net sales of licensed products subject to a \$25,000 minimum annual royalty. Navidea also agreed to reimburse UCSD for all patent-related costs and to meet certain diligence targets.

## <u>Manocept Platform – Immuno-Diagnostics Clinical Data</u>

#### Rheumatoid Arthritis

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

#### Cardiovascular Disease

Results of our studies to date (ClinicalTrials.gov NCT02542371) provide strong evidence of the potential of Tc99m tilmanocept to accumulate in high risk morphology plaques, the ability to make preliminary comparisons of aortic Tc99m tilmanocept uptake by SPECT/CT in clinically symptomatic patients vs. healthy age-matched subjects, and to evaluate the ability of Tc99m tilmanocept to identify the same aortic atherosclerotic plaques that are identified by contrast enhanced coronary computed tomography angiography and/or PET/CT. A second study has been initiated in subjects with Human Immunodeficiency Virus ("HIV") that greatly expands the original study in both the scope of the drug administration as well as the diagnostic assessment of the subjects. We anticipate results in the second or third quarter of 2018.

#### Nonalcoholic Steatohepatitis

The Company has initiated a clinical study examining the safety and efficacy of Tc99m radiolabel escalation of IV-injected Tc99m tilmanocept in SPECT/CT imaging studies to identify and quantify the extent of NASH lesions in human patients. The study already has results and we anticipate presenting some limited results in during the first half of 2018 (ClinicalTrials.gov NCT03332940).

## Other Immuno-Diagnostic Applications

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

## 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 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." Post-meeting with the FDA and because of Navidea's overwhelming 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 is revising the LOI draft strategy in order to expedite the application process. Since the meeting, Navidea has gathered extensive new data that bear on this qualification strategy. On March 1, 2018, Navidea had a follow-up meeting with the FDA's assigned strategist and further narrowing of the LOI elements were reviewed. Navidea is continuing the process of finalizing the LOI COU and providing the background data sets for qualification review with the FDA/CDER.

## Macrophage Therapeutics Background

In December 2014, the Company formed a new business unit to further explore therapeutic applications for the Manocept platform. In January 2015, Navidea incorporated the business unit as MT, a majority-owned subsidiary of Navidea. Navidea also granted MT an exclusive license for certain therapeutic applications of the Manocept technology.

MT has developed processes for producing the first two therapeutic Manocept immuno-constructs, MT-1002, designed to specifically target and kill activated CD206+ macrophages by delivering doxorubicin, and MT-2002, designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent. MT has contracted with independent facilities to produce sufficient quantities of the MT-1002 and MT-2002 agents along with the concomitant analytical standards, to provide material for planned preclinical animal studies and future clinical trials.

## <u>Manocept Platform - In-Vitro and Pre-Clinical Immunotherapeutics Data</u>

The novel MT-1002 construct is designed to specifically deliver doxorubicin, a chemotoxin, which can kill KS tumor cells and their tumor-associated macrophages potentially altering the course of cancer. KS is a serious and potentially life threatening illness in persons infected with HIV and the third leading cause of death in this population worldwide. The prognosis for patients with KS is poor with high probabilities for mortality and greatly diminished quality of life. The funds for this Fast Track grant will be released in three parts, which together have the potential to provide up to \$1.8 million in resources over 2.5 years with the goal of completing an IND submission for a Manocept construct (MT-1000 class of compounds) consisting of tilmanocept linked to doxorubicin for the treatment of KS. The first part of the grant provided \$232,000 to support analyses including in vitro and cell culture studies now complete and will be followed by Part 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).

Navidea and MT continue to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform, including ongoing studies in KS, 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.

Navidea and MT 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 Navidea and MT continue this work funded by the NIH/NIAID and NCI.

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

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

Navidea and MT 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 Navidea and MT continue this work funded by the NIH/NIAID and NCI.

We have completed an expanded series of predictive in vitro screening tests of the MT-1002 and MT-2002 therapeutic conjugates against the Zika and Dengue viruses, which included infectivity and viral replication inhibition effectiveness as well as dose finding studies and mechanisms of action, the latter based on conjugate structures. We have also completed a series of predictive in vivo screening tests of the MT-1002 and MT-2002 therapeutic conjugates against Leishmaniosis, which included host cell targeting and killing effectiveness as well as dose finding studies and mechanisms of action. A portion of the results from the *in vivo* Leishmaniosis study, completed in conjunction with the National Institute of Allergy and Infectious Diseases/NIH, was recently published in the *Journal of Experimental Medicine* (published in the circulated version *Journal of Experimental Medicine* 2018 Jan 2;215(1):357-375). The results from all evaluations were positive and have provided a basis for moving forward with additional *in vivo* testing of the selected conjugates. We have selected collaborators for these *in vivo* studies, which we expect will take place over the next four to six months. We will provide updates as information becomes available on future testing. However, we cannot assure you that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance. See Risk Factors.

#### NAV4694 (Candidate for Divestiture)

NAV4694 is a fluorine-18 ("F-18") labeled PET imaging agent being developed as an aid in the imaging and evaluation of patients with signs or symptoms of Alzheimer's disease ("AD") and mild cognitive impairment ("MCI"). NAV4694 binds to beta-amyloid deposits in the brain that can then be imaged in PET scans. Amyloid plaque pathology is a required feature of AD and the presence of amyloid pathology is a supportive feature for diagnosis of probable AD. Patients who are negative for amyloid pathology do not have AD. NAV4694 has been studied in rigorous pre-clinical studies and clinical trials in humans. Clinical studies through Phase 3 have included subjects with MCI, suspected AD patients, and healthy volunteers. Results suggest that NAV4694 has the potential ability to image patients quickly and safely with high sensitivity and specificity.

In May 2014, the Board of Directors made the decision to refocus the Company's resources to better align the funding of our pipeline programs with the expected growth in 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. Discussions related to the potential partnering or divestiture of NAV4694 were delayed due in large part to litigation brought by Sinotau, one of the potential partners. In August 2015, Sinotau filed a suit for damages, specific performance, and injunctive relief against the Company in the U.S. District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company's NAV4694 product candidate and technology. In September 2016, the Court denied the Company's motion to dismiss. The Company filed its answer to the complaint and the parties have filed multiple joint motions to stay the case pending settlement discussion, which to date have been granted. On October 26, 2017, the Company executed a letter of intent with Sinotau and Cerveau, outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims.

## NAV5001 (In-License Terminated)

NAV5001 is an iodine-123 labeled SPECT imaging agent being developed as an aid in the diagnosis of Parkinson's disease ("PD") and other movement disorders, with potential use as a diagnostic aid in dementia. The agent binds to the dopamine transporter ("DAT") on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a hallmark of PD. In addition to its potential use as an aid in the differential diagnosis of PD and movement disorders, NAV5001 may also be useful in the diagnosis of Dementia with Lewy Bodies, one of the most common forms of dementia after AD.

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

In April 2015, the Company entered into an agreement with Alseres to terminate the sub-license agreement, dated July 31, 2012, for research, development and commercialization of NAV5001. Under the terms of this agreement, Navidea transferred all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres agreed to reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, Navidea has supplied clinical support services for NAV5001 on a cost-plus reimbursement basis. However, to this point, Alseres has been unsuccessful in raising the funds necessary to restart the program and reimburse Navidea. As a result, we have taken steps to end our obligations under the agreement and notified Alseres that we consider them in breach of the agreement. To date, we have not been successful in our efforts to recover the funds we expended complying with our obligations under the termination agreement.

### **Market Overview**

Tc99m Tilmanocept – Cancer Market Overview

Cancer is the second leading cause of death in both the United States and Europe. The American Cancer Society ("ACS") estimates that cancer will cause over 600,000 deaths in 2018 in the United States alone. Additionally, the ACS estimates that approximately 1.7 million new cancer cases will be diagnosed in the United States during 2018. For the types of cancer to which our oncology agents may be applicable (breast, melanoma, head and neck, prostate, lung, colorectal, gastrointestinal and gynecologic), the ACS has estimated that over 1.2 million new cases will occur in the United States in 2018. 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.

Currently, the application of intraoperative lymphatic mapping ("ILM") is most established in breast cancer. Breast cancer is the second leading cause of death from cancer among all women in the United States The probability of developing breast cancer generally increases with age, rising from about 1.9% in women under age 49 to 6.8% in women age 70 or older. According to the ACS, over 268,000 new cases of breast cancer are expected to be diagnosed during 2018 in the United States alone.

The use of ILM is also common in melanoma. The ACS estimates that approximately 91,000 new cases of melanoma will be diagnosed in the United States during 2018. In addition to breast cancer and melanoma, we believe that our oncology products may have utility in other cancer types with another 806,000 new cases expected during 2018 in the United States.

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, head and neck, gynecologic, and non-small cell lung. 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, 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.

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 and perhaps 700 million worldwide, making these macrophage-mediated diseases an area of remarkable clinical importance. RA alone affects over 1.3 million people in the United States and as much as 1% of the worldwide population. Data from studies using agents from the Manocept platform in RA, KS and TB were published in a special supplement, *Nature Outlook: Medical Imaging*, in *Nature's* October 31, 2013 issue. The supplement included a White Paper by Navidea entitled "*Innovations in receptor-targeted precision imaging at Navidea: Diagnosis up close and personal*," focused on the Manocept platform.

#### NAV4694 - Alzheimer's Disease Market Overview

The Alzheimer's Association ("AA") estimates that more than 5.5 million Americans had AD in 2017. 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. AA estimates that total costs for AD care was approximately \$259 billion in 2017. AA also estimates that there are over 15 million AD and dementia caregivers providing 18.2 billion hours of unpaid care valued at over \$230 billion. 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 2000-2014, deaths from AD have risen 89 percent while deaths attributed to the number one cause of death, heart disease, decreased 14 percent during the same period.

## **Marketing and Distribution**

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

Unlike the United States, where institutions typically rely on radiopharmaceutical products which are compounded and delivered by specialized radiopharmacy distributors such as Cardinal Health 414, institutions in Europe predominantly purchase non-radiolabeled material and compound the radioactive product on-site. With respect to Tc99m tilmanocept commercialization in Europe, we have chosen a specialty pharmaceutical strategy that should be supportive of premium product positioning and reinforce Tc99m tilmanocept's clinical value proposition, as opposed to a commodity or a generics positioning approach. In March 2015, we entered into an exclusive sublicense agreement for the commercialization and distribution of a 50 microgram kit for radiopharmaceutical preparation (tilmanocept) in the European Union ("EU") with SpePharm AG (an affiliate of Norgine BV), a European specialist pharmaceutical company with an extensive pan-European presence. Under the terms of the exclusive license agreement, Navidea transferred responsibility for regulatory maintenance of the Tc99m tilmanocept Marketing Authorization to SpePharm in January 2017. SpePharm is also responsible for production, distribution, pricing, reimbursement, sales, marketing, medical affairs, and regulatory activities. In connection with entering into the agreement, Navidea received an upfront payment of \$2.0 million, and is entitled to milestones totaling up to an additional \$5.0 million and royalties on European net sales. The initial territory covered by the agreement includes all 28 member states of the European Economic Community with the option to expand into additional geographical areas. During the second quarter of 2017, SpePharm launched Tc99m tilmanocept in select EU markets, providing a number of early adopters with sample doses to provide exposure to the product. EU sales commenced during the third quarter of 2017.

In August 2014, Navidea entered into an exclusive agreement with Sinotau, a pharmaceutical organization with a broad China focus in oncology and other therapeutic areas, who will develop and commercialize Tc99m tilmanocept in China. In exchange, Navidea will earn revenue based on unit sales to Sinotau, royalties based on Sinotau's sales of Tc99m tilmanocept and milestone payments from Sinotau, including a \$300,000 non-refundable upfront payment. As part of the agreement, Sinotau is responsible for costs and conduct of clinical studies and regulatory applications to obtain Tc99m tilmanocept approval by the China Food and Drug Administration ("CFDA"). Upon approval, Sinotau will be responsible for all Tc99m tilmanocept sales, marketing, market access and medical affairs activities in China and excluding Hong Kong, Macau and Taiwan. Navidea and Sinotau will jointly support certain pre-market planning activities with a joint commitment on clinical and market development programs pending CFDA approval. On February 1, 2017, Navidea filed a suit against Sinotau, and on February 2, 2017, Sinotau filed a suit against the Company and Cardinal Health 414. On February 8, 2018, Navidea and Sinotau executed an amendment to the agreement, modifying certain terms of the agreement and effectively resolving the legal dispute. On February 17, 2018, Navidea and Sinotau executed a Settlement Agreement and Mutual Release, and on February 20, 2018, Navidea and Sinotau voluntarily dismissed their legal cases. See Item 3 – Legal Proceedings.

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 U.S. 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 Risk Factors.

## Manufacturing

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

In November 2009, we completed a Manufacture and Supply Agreement with Reliable Biopharmaceutical Corporation ("Reliable") for the manufacture of the bulk drug substance with an initial term of 10 years. In September 2013, we entered into a Manufacturing Services Agreement with OSO BioPharmaceuticals Manufacturing, LLC ("OsoBio") for contract pharmaceutical development, manufacturing, packaging and analytical services for Tc99m tilmanocept. Also in September 2013, we completed a Service and Supply Master Agreement with Gipharma S.r.l. ("Gipharma") for process development, manufacturing and packaging of reduced-mass vials for sale in the EU. Upon closing of the Asset Sale to Cardinal Health 414, our contracts with Reliable and OsoBio were transferred to Cardinal Health 414. Similarly, following the transfer of the Tc99m tilmanocept Marketing Authorization to SpePharm, our contract with Gipharma was transferred to SpePharm. We may not be successful in completing future agreements for the supply of Tc99m tilmanocept on terms acceptable to the Company, or at all. See Risk Factors.

## Competition

Competition in the pharmaceutical and biotechnology industries is intense. We face competition from a variety of companies focused on developing oncology and neurology diagnostic drugs. We compete with large pharmaceutical and other specialized biotechnology companies. We also face competition from universities and other non-profit research organizations. Many emerging medical product companies have corporate partnership arrangements with large, established companies to support the research, development, and commercialization of products that may be competitive with our products. In addition, a number of large established companies are developing proprietary technologies or have enhanced their capabilities by entering into arrangements with or acquiring companies with technologies applicable to the detection or treatment of cancer and other diseases targeted by our product candidates. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of these competitors have products that have been approved or are in development and operate large, well-funded research and development programs. Many of our existing or potential competitors have substantially greater financial, research and development, regulatory, marketing, and production resources than we have. Other companies may develop and introduce products and processes competitive with or superior to ours.

We expect to encounter significant competition for our pharmaceutical products. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before us may achieve a significant competitive advantage if their products work through a similar mechanism as our products and if the approved indications are similar. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us. In some instances, such products have already entered late-stage clinical trials or received FDA approval and may be marketed for some period prior to the approval of our products.

We believe that our ability to compete successfully will be based on our ability to create and maintain scientifically advanced "best-inclass" technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market our products, either alone or through third parties. We expect that competition among products cleared for marketing will be based on, among other things, product efficacy, safety, reliability, availability, price, and patent position. See Risk Factors.

#### Tc99m Tilmanocept Competition

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."

#### NAV4694 Competition

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

#### **Patents and Proprietary Rights**

The patent position of biotechnology 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 Risk Factors.

#### Tilmanocept Intellectual Property

Tilmanocept is under license from UCSD to Navidea for the exclusive world-wide rights in all diagnostic and therapeutic uses of tilmanocept, except for the diagnostic use of Tc99m tilmanocept in Canada, Mexico and the United States, which rights have been licensed directly to Cardinal Health 414 by UCSD in connection with the Asset Sale. Navidea maintains license rights to Tc99m tilmanocept in the rest of the world, as well as a license to the intellectual property underlying the Manocept platform.

Tc99m tilmanocept and related compositions, including the Manocept backbone composition and methods of use, are the subject of multiple patent families totaling 43 patents and patent applications in the United States and certain major foreign markets.

The first composition of matter patent covering tilmanocept was issued in the United States in June 2002. This patent will expire in May 2020, but a request for patent term extension has been filed to further extend the life of this patent. The claims of the composition of matter patent covering tilmanocept have been allowed in the EU and issued in the majority of major-market EU countries in 2004. These patents will expire in 2020, but a request for supplemental protection certificates are in process to further extend the life of these patents, and some have been granted, extending the patent term to 2025. The composition of matter patent has also been issued in Japan, which will expire in 2020

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

#### NAV4694 Intellectual Property

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

## **Government Regulation**

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, Public Health Service Act, and their implementing regulations. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications or supplemental applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution. We also may be subject to regulation under the Occupational Safety and Health Act, the Atomic Energy Act, the Toxic Substances Control Act, the Export Control Act and other present and future laws of general application as well as those specifically related to radiopharmaceuticals.

Most aspects of our business are subject to some degree of government regulation in the countries in which we conduct our operations. As a developer, manufacturer and marketer of medical products, we are subject to extensive regulation by, among other governmental entities, the FDA and the corresponding state, local and foreign regulatory bodies in jurisdictions in which our products are intended to be sold. These regulations govern the introduction of new products, the observance of certain standards with respect to the manufacture, quality, safety, efficacy and labeling of such products, the maintenance of certain records, the tracking of such products, performance surveillance and other matters.

Failure to comply with applicable federal, state, local or foreign laws or regulations could subject us to enforcement action, including product seizures, recalls, withdrawal of marketing clearances, and civil and criminal penalties, any one or more of which could have a material adverse effect on our business. We believe that we are in substantial compliance with such governmental regulations. However, federal, state, local and foreign laws and regulations regarding the manufacture and sale of radiopharmaceuticals are subject to future changes. 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 Risk Factors.

In the early- to mid-1990s, the review time by the FDA to clear medical products for commercial release lengthened and the number of marketing clearances decreased. In response to public and congressional concern, the FDA Modernization Act of 1997 (the "1997 Act") was adopted with the intent of bringing better definition to the clearance process for new medical products. While the FDA review times have improved since passage of the 1997 Act, the FDA review processes could delay our Company's introduction of new products in the United States in the future. In addition, many foreign countries have adopted more stringent regulatory requirements that also have added to the delays and uncertainties associated with the development and release of new products, as well as the clinical and regulatory costs of supporting such releases. It is possible that delays in receipt of, or failure to receive, any necessary clearance for our new product offerings could have a material adverse effect on our business, financial condition or results of operations. See 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 EC 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 <a href="http://www.navidea.com">http://www.navidea.com</a>. We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and amendments to such filings, as soon as reasonably practicable after each is electronically filed with, or furnished to, the Securities Exchange Commission ("SEC"). We do not charge for access to and viewing of these reports. Information in the investor section and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference.

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

#### **Financial Statements**

Our consolidated financial statements and the related notes, including revenues, income (loss), total assets and other financial measures are set forth at pages F-1 through F-41 of this Form 10-K.

## **Research and Development**

We spent approximately \$4.5 million, \$7.1 million and \$10.6 million on research and development activities in the years ended December 31, 2017, 2016 and 2015, respectively.

### **Employees**

As of March 1, 2018, we had 19 full-time and 5 part-time employees. None of our employees are represented by a collective bargaining agreement, we have not experienced any work stoppages, and we believe that our relationship with our employees is good.

## Item 1A. Risk Factors

An investment in our common stock is highly speculative, involves a high degree of risk, and should be made only by investors who can afford a complete loss. You should carefully consider the following risk factors, together with the other information in this Form 10-K, including our financial statements and the related notes, before you decide to buy our common stock. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading of our common stock could decline, and you may lose all or part of your investment therein.

If Cardinal Health 414, SpePharm AG or Sayre Therapeutics do not achieve commercial success with Tc99m tilmanocept, we may be unable to generate significant revenue or become profitable.

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

We announced an exclusive EU distribution partnership for Tc99m tilmanocept with SpePharm AG, a subsidiary of Norgine B.V., in March 2015, and SpePharm commenced marketing of Tc99m tilmanocept in the EU during the third quarter of 2017. Navidea is entitled to receive royalty and milestone payments from SpePharm based on net sales derived from Tc99m tilmanocept.

In June 2017, Navidea entered into an exclusive license and distribution agreement with Sayre for the development and commercialization of Tc99m tilmanocept in India. Under the terms of the agreement, 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 or Sayre may never achieve commercial success in North America, the EU, India, 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.

We continue to seek to partner or sub-license NAV4694. In October 2017, the Company executed a letter of intent with Sinotau and Cerveau, outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims. See Item 3 – Legal Proceedings. Pending resolution of the Sinotau litigation, we continue to incur costs to maintain our ability to support future clinical evaluation of this product candidate to preserve it for eventual sub-licensing.

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

- they are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;
- we are able to commercialize them in clinical development or sell the marketing rights to third parties; and
- upon being developed, they are approved by the regulatory authorities.

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

We may never obtain regulatory approval to manufacture or market our unapproved drug candidates and our approval to market our products or anticipated commercial launch may be delayed as a result of the regulatory review process.

Obtaining regulatory approval to market drugs to diagnose or treat diseases is expensive, difficult and risky. Preclinical and clinical data, as well as information related to the chemistry, manufacturing and control ("CMC") processes of drug production, can be interpreted in different ways that could delay, limit or preclude regulatory approval. Negative or inconclusive results, adverse medical events during a clinical trial, or issues related to CMC processes could also delay, limit or prevent regulatory approval. Even if we receive regulatory clearance to market a particular product candidate, the approval could be conditioned on us conducting additional costly post-approval studies or could limit the indicated uses included in our labeling.

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

We may not be able to secure and/or maintain agreements or other purchasing arrangements with our subcontractors on terms acceptable to us, or that our subcontractors will be able to meet our production requirements on a timely basis, at the required levels of performance and quality, including compliance with FDA cGMP requirements. In the event that any of our subcontractors are unable or unwilling to meet our production requirements, we may not be able to establish an alternate source of supply without significant interruption in product supply or without significant adverse impact to product availability or cost. Any significant supply interruption or yield problems that we or our subcontractors experience would have a material adverse effect on our ability to manufacture our products and, therefore, a material adverse effect on our business, financial condition, and results of operations until a new source of supply is qualified.

Clinical trials for our product candidates will be lengthy and expensive, and their outcome is uncertain.

Before obtaining regulatory approval for the commercial sale of any product candidates, we must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting clinical trials is a time consuming, expensive and uncertain process and may take years to complete.

We expect to sponsor efforts to explore the Manocept platform, whether in potential diagnostic or therapeutic uses. We continually assess our clinical trial plans and may, from time to time, initiate additional clinical trials to support our overall strategic development objectives. Historically, the results from preclinical testing and early clinical trials often do not predict the results obtained in later clinical trials. Frequently, drugs that have shown promising results in preclinical or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. At any time during the clinical trials, we, the participating institutions, the FDA, the EMA or other regulatory authorities might delay or halt any clinical trials for our product candidates for various reasons, including:

- ineffectiveness of the product candidate;
- discovery of unacceptable toxicities or side effects;
- development of disease resistance or other physiological factors;
- delays in patient enrollment; or
- other reasons that are internal to the businesses of our potential collaborative partners, which reasons they may not share with us.

While we have achieved some level of success in our clinical trials for Tc99m tilmanocept as indicated by the FDA and EMA approvals, the results of pending and future trials for other product candidates that we may develop or acquire, are subject to review and interpretation by various regulatory bodies during the regulatory review process and may ultimately fail to demonstrate the safety or effectiveness of our product candidates to the extent necessary to obtain regulatory approval, or that commercialization of our product candidates is worthwhile. Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates could materially harm our business.

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

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

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

Prior to commercialization, each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. The development of radiopharmaceutical technologies and compounds, including those we are currently developing, is unpredictable and subject to numerous risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons including that they may:

- be found ineffective or cause harmful side effects during preclinical testing or clinical trials;
- fail to receive necessary regulatory approvals;
- be difficult to manufacture on a scale necessary for commercialization;
- be uneconomical to produce;
- fail to achieve market acceptance; or
- be precluded from commercialization by proprietary rights of third parties.

The occurrence of any of these events could adversely affect the commercialization of our product candidates. Products, if introduced, may not be successfully marketed and/or may not achieve customer acceptance. If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

If we fail to establish and maintain collaborations or if our partners do not perform, we may be unable to develop and commercialize our product candidates.

We have entered into collaborative arrangements with third parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. Such collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline.

Our dependence on collaborative arrangements with third parties will subject us to a number of risks that could harm our ability to develop and commercialize products including that:

- collaborative arrangements may not be on terms favorable to us;
- disagreements with partners or regulatory compliance issues may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;
- we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;
- partners may choose to develop, independently or with other companies, alternative products or treatments. including products
  or treatments which compete with ours;
- agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us:
- business combinations or significant changes in a partner's business strategy might adversely affect that partner's willingness
  or ability to complete its obligations to us; and
- the terms and conditions of the relevant agreements may no longer be suitable.

The occurrence of any of these events could adversely affect the development or commercialization of our products.

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

Approved products may later cause adverse effects that limit or prevent their widespread use, force us to withdraw it from the market or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, any contract manufacturer we use in the process of producing a product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing clearance, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will remain subject to extensive regulatory requirements. We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines:
- injunctions;
- product seizures or detentions;
- import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations such as health maintenance organizations ("HMOs"). Generally, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payer of patients' healthcare costs. Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to further reform health care or reduce government insurance programs, may all result in lower prices for our products if approved for commercialization. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to sell our products at a profit.

We may be unable to establish or contract for the pharmaceutical manufacturing capabilities necessary to develop and commercialize our potential products.

We are in the process of establishing third-party clinical manufacturing capabilities for our compounds under development. We intend to rely on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of our potential products. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, clinical trials for our product candidates may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products, and for approved products, any such delays, interruptions or other difficulties may render us unable to supply sufficient quantities to meet demand. Any such delays or interruptions may lower our revenues and potential profitability.

We and any third-party manufacturers that we may use must continually adhere to cGMPs and regulations enforced by the FDA through its facilities inspection program and/or foreign regulatory authorities where our products will be tested and/or marketed. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, the FDA and/or foreign regulatory authorities will not grant approval to market our product candidates. In complying with these regulations and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort on production, record-keeping and quality control to assure that our potential products meet applicable specifications and other requirements. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs.

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

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

The biotech and pharmaceutical industries are intensely competitive. Many of our competitors have significantly greater financial, technical, manufacturing, marketing and distribution resources as well as greater experience in the industry than we have. The particular medical conditions our product lines address can also be addressed by other medical procedures or drugs. Many of these alternatives are widely accepted by physicians and have a long history of use.

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

Physicians may use our competitors' products and/or our products may not be competitive with other technologies. Tc99m tilmanocept is expected to continue to compete against sulfur colloid in the United States and other colloidal agents in the EU and other global markets. If our competitors are successful in establishing and maintaining market share for their products, our future earnout and royalty receipts may not occur at the rate we anticipate. In addition, our potential competitors may establish cooperative relationships with larger companies to gain access to greater research and development or marketing resources. Competition may result in price reductions, reduced gross margins and loss of market share.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We continue to seek to partner or sub-license NAV4694, which is designed to enable PET imaging of beta-amyloid deposits in the brain, believed to correlate with the presence of AD. In October 2017, the Company executed a letter of intent with Sinotau and Cerveau, outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims. See Item 3 – Legal Proceedings. Pending resolution of the Sinotau litigation, we continue to incur costs to maintain our ability to support future clinical evaluation of this product candidate to preserve it for eventual sub-licensing.

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

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

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

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 US 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 Texas CRG litigation and other litigation;
- the costs of seeking regulatory approval for our product candidates, including any nonclinical testing or bioequivalence or clinical studies, process development, scale-up and other manufacturing and stability activities, or other work required to achieve such approval, as well as the timing of such activities and approval;
- the extent to which we invest in or acquire new technologies, product candidates, products or businesses and the development requirements with respect to any acquired programs;
- the scope, prioritization and number of development and/or commercialization programs we pursue and the rate of progress and costs with respect to such programs;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities and regulatory compliance capabilities, if we commercialize any of our product candidates for which we obtain regulatory approval without a partner;
- the timing and terms of any collaborative, licensing and other strategic arrangements that we may establish;

- the extent to which we may need to expand our workforce to pursue our business plan, and the costs involved in recruiting, training, compensating and incentivizing new employees;
- the effect of competing technological and market developments; and
- the cost involved in establishing, enforcing or defending patent claims and other intellectual property rights.

If we are unsuccessful in raising additional capital, or the terms of raising such capital are unacceptable, we may have to modify our business plan and/or significantly curtail our planned development activities, acquisition of new product candidates and other operations.

There may be future sales or other dilution of our equity, which may adversely affect the market price of shares of our common stock.

Our existing warrants or other securities convertible into or exchangeable for our common stock, or securities we may issue in the future, may contain adjustment provisions that could increase the number of shares issuable upon exercise, conversion or exchange, as the case may be, and decrease the exercise, conversion or exchange price. The market price of our shares of common stock could decline as a result of sales of a large number of shares of our common stock or other securities in the market, the triggering of any such adjustment provisions or the perception that such sales could occur in the future.

The final outcome of the Texas CRG litigation may require us to pay up to an additional \$7.0 million, which would adversely affect our financial position.

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

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59.0 million (the "Deposit Amount") of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in the Texas Court to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents (the "Final Payoff Amount"). The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47.0 million (the "Low Payoff Amount") and no more than \$66.0 million (the "High Payoff Amount"). In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7.0 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12.0 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59.0 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2.0 million being held in escrow pursuant to court order in the Ohio case and the \$3.0 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7.0 million letter of credit, and on March 7, 2017, CRG posted a \$12.0 million letter of credit, each as required by the Global Settlement Agreement.

The trial was held in Texas in December 2017. The Texas Court ruled that the Company's total obligation to CRG is 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 owes 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. The Company believes that this \$4.1 million should be credited against the \$7 million; CRG disagrees. On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the Texas Court's oversight of not explaining how to apply the \$4.1 million payment, requesting that the judgment be modified to set the supersedeas amount at \$2.9 million so that the Company can stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. The Texas Court has scheduled a hearing on the issue for March 26, 2018, however it has not yet set the amount, and enforcement of the judgment is stayed until seven days after the Texas Court does so. We currently await further action by the Texas Court. If we are ultimately required to pay an additional \$7.0 million to CRG, such payment would have a significant adverse effect on our financial position and would likely force us to curtail our planned development activities.

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

Shares of our common stock are common equity interests. This means that our common stock ranks junior to any preferred stock that we may issue in the future, to our indebtedness and to all creditor claims and other non-equity claims against us and our assets available to satisfy claims on us, including claims in a bankruptcy or similar proceeding. Our future indebtedness and preferred stock may restrict payments of dividends on our common stock.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our Board of Directors or a duly authorized committee of our Board of Directors, and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to shareholders generally.

The continuing contentious federal budget negotiations may have an impact on our business and financial condition in ways that we currently cannot predict, and may further limit our ability to raise additional funds.

The continuing federal budget disputes not only may adversely affect financial markets, but could also delay or reduce research grant funding and adversely affect operations of government agencies that regulate us, including the FDA, potentially causing delays in obtaining key regulatory approvals. 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 since February 2011. The rules of NYSE American provide that shares be delisted from trading in the event the financial condition and/or operating results of the Company appear to be unsatisfactory, the extent of public distribution or the aggregate market value of the common stock has become so reduced as to make further dealings on the NYSE American inadvisable, the Company has sold or otherwise disposed of its principal operating assets, or has ceased to be an operating company, or the Company has failed to comply with its listing agreements with the Exchange. For example, the NYSE American may consider suspending trading in, or removing the listing of, securities of an issuer that has stockholders' equity of less than \$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, 2017, the Company had stockholders' equity of approximately \$12.0 million. However, the Company had stockholders' deficits for several years prior to December 31, 2017, and we may not be able to maintain stockholders' equity in the future. Even if an issuer has a stockholders' deficit, the NYSE American will not normally consider removing from the list securities of an issuer that fails to meet these requirements if the issuer has (1) total value of market capitalization of at least \$50,000,000; or total assets and revenue of \$50,000,000 each in its last fiscal year, or in two of its last three fiscal years; and (2) the issuer has at least 1,100,000 shares publicly held, a market value of publicly held shares of at least \$15,000,000 and 400 round lot shareholders. Based on the number of outstanding shares of our common stock, recent trading price of that stock, and number of round lot holders, we believe that we meet these exception criteria and that our common stock will not be delisted as a result of our failure to meet the minimum stockholders' equity requirement for continued listing. The Company may not be able to continue to meet these and other requirements necessary to maintain the listing of our common stock on the NYSE American. For example, we may determine to grow our organization or product pipeline or pursue development or other activities at levels or on timelines that reduces our stockholders' equity below the level required to maintain compliance with NYSE American continued listing standards.

The NYSE American Company Guide also provides that the Exchange may suspend or remove from listing any common stock selling for a substantial period of time at a low price per share, if the issuer shall fail to effect a reverse split of such shares within a reasonable time after being notified that the Exchange deems such action to be appropriate under all the circumstances. The Company's common stock has recently traded for a price as low as \$0.31 per share, and if the low trading price persists, there is a risk that the Exchange may require the Company to effect a reverse split of its common stock in order to maintain its NYSE American listing, and that the shares will be delisted if such action is not taken to the satisfaction of the NYSE American.

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, which is critical to the execution of our current business strategy.

The price of our common stock has been highly volatile due to several factors that will continue to affect the price of our stock.

Our common stock traded as low as \$0.31 per share and as high as \$0.85 per share during the 12-month period ended February 28, 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 our common stock may be limited by trading volume.

During the 12-month period beginning on March 1, 2017 and ending on February 28, 2018, the average daily trading volume for our common stock on the NYSE American was approximately 435,000 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 management team could have an adverse effect on our operations. Our success depends on our ability to attract and retain technical and management personnel with expertise and experience in the pharmaceutical industry, and the acquisition of additional product candidates may require us to acquire additional highly qualified personnel. The competition for qualified personnel in the biotechnology industry is intense and we may not be successful in hiring or retaining the requisite personnel. If we are unable to attract and retain qualified technical and management personnel, we will suffer diminished chances of future success.

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.

Attempts to repeal or to repeal and replace the PPACA will likely continue under the current Congress. 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.

#### **Item 1B. Unresolved Staff Comments**

None

#### **Item 2. Properties**

We currently lease approximately 5,000 square feet of office space at 4995 Bradenton Avenue, Dublin, Ohio, as our principal offices. The current least term expires in June 2020, at a monthly base rent of approximately \$3,000. We must also pay a pro-rata portion of the operating expenses and real estate taxes of the building. We also lease approximately 2,000 square feet of office space at 560 Sylvan Avenue, Englewood Cliffs, New Jersey. The current lease term expires in March 2018, at a monthly base rent of approximately \$3,000. We must also pay a pro-rata portion of the electricity costs of the building. The New Jersey office is primarily for the use of Dr. Goldberg and Mr. Latkin and the planned hires in business and corporate development for both Navidea and Macrophage Therapeutics. We believe that this location improves our access to qualified candidates, as it is located in close proximity to the headquarters of many large pharmaceutical companies which are located in New York City and New Jersey. It also places our senior management closer to the institutional investors who are the thought leaders in the life science investing marketplace. We believe both facilities are in good condition.

We also currently lease approximately 25,000 square feet of office space at 5600 Blazer Parkway, Dublin, Ohio, formerly our principal offices. The current lease term expires in October 2022, at a monthly base rent of approximately \$26,000 during 2018. We must also pay a pro-rata portion of the operating expenses and real estate taxes of the building. In June 2017, the Company executed a sublease arrangement for the Blazer space, providing for monthly sublease payments to Navidea of approximately \$39,000 through October 2022.

## Item 3. Legal Proceedings

Sinotau Litigation – NAV4694

On August 31, 2015, Sinotau filed a suit for damages, specific performance, and injunctive relief against the Company in the U.S. District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company's NAV4694 product candidate and technology (the "Sinotau Litigation"). In September 2016, the Court denied the Company's motion to dismiss. The Company filed its answer to the complaint and the parties have filed multiple joint motions to stay the case pending settlement discussion, which to date have been granted. On October 26, 2017, the Company executed a letter of intent with Sinotau and Cerveau, outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims.

## CRG Litigation

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas on 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 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59.0 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47.0 million and no more than \$66.0 million. In addition, CRG agreed that Navidea had the right to assert all affirmative defenses to its claim of default. In the underlying case the district court had entered summary judgment in favor of CRG finding unspecified events of default but refusing to consider affirmative defenses raised by Navidea as not before the Court. Subsequent to the settlement CRG moved again for entry of judgment in its favor; Navidea objected that the Settlement Agreement specifically allowed it to raise affirmative defenses and the district court agreed with Navidea setting the case for trial in December 2017. CRG once again moved for summary judgment and the motion was heard by the Court on October 30, 2017.

Concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a \$7.0 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a \$12.0 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59.0 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2.0 million being held in escrow pursuant to court order in the Ohio case and the \$3.0 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale.

The trial was held in Texas in December 2017. The Texas Court ruled that the Company's total obligation to CRG is 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 owes 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. The Company believes that this \$4.1 million should be credited against the \$7 million; CRG disagrees. On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the Texas Court's oversight of not explaining how to apply the \$4.1 million payment, requesting that the judgment be modified to set the supersedeas amount at \$2.9 million so that the Company can stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. The Texas Court has scheduled a hearing on the issue for March 26, 2018, however it has not yet set the amount, and enforcement of the judgment is stayed until seven days after the Texas Court does so. We currently await further action by the Texas Court.

Navidea's management believes it is probable that the Company will be required to pay the \$2.9 million modified judgment requested in January 2018, and as such we accrued a loss contingency for that amount as a current liability on the December 31, 2017 consolidated balance sheet. The loss contingency of \$2.9 million was recorded as an additional loss on extinguishment of the CRG Term Loan on the consolidated statement of operations for the year ended December 31, 2017.

#### Former CEO Arbitration

On May 12, 2016 the Company received a demand for arbitration through the American Arbitration Association, Columbus, Ohio, from Ricardo J. Gonzalez, the Company's then Chief Executive Officer, claiming that he was terminated without cause and, alternatively, that he resigned in accordance with Section 4G of his Employment Agreement pursuant to a notice received by the Company on May 9, 2016. On May 13, 2016, the Company notified Mr. Gonzalez that his failure to undertake responsibilities assigned to him by the Board of Directors and otherwise work after being ordered to do so on multiple occasions constituted an effective resignation, and the Company accepted that resignation. The Company rejected the resignation of Mr. Gonzalez pursuant to certain provisions in Section 4G of his Employment Agreement. Also, the Company notified Mr. Gonzalez that, alternatively, his failure to return to work after the expiration of the cure period provided in his Employment Agreement constituted cause for his termination under his Employment Agreement. Mr. Gonzalez was seeking severance and other amounts claimed to be owed to him under his Employment Agreement. In response, the Company filed counterclaims against Mr. Gonzalez alleging malfeasance by Mr. Gonzalez in his role as Chief Executive Officer. Mr. Gonzalez withdrew his claim for additional severance pursuant to his Employment Agreement, and the Company withdrew its counterclaims. On May 12, 2017, the Company received a ruling in favor of Mr. Gonzalez finding that he was terminated by the Company without cause on April 7, 2016. Mr. Gonzalez was awarded salary, bonus, and benefits in the aggregate amount of \$481,039 plus interest, attorneys' fees, and other costs. The arbitration award is final and binding on the parties. The Company paid an aggregate of \$617,880 to Mr. Gonzalez on May 16, 2017.

#### FTI Consulting, Inc. Litigation

On October 11, 2016, FTI Consulting, Inc. ("FTI") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in excess of \$782,600 comprised of: (i) \$730,264 for investigative and consulting services FTI alleges to have provided to the Company pursuant to an Engagement Agreement between FTI and the Company, and (ii) in excess of \$52,337 for purported interest due on unpaid invoices, plus attorneys' fees, costs and expenses. On November 14, 2016, the Company filed an Answer and Counterclaim denying the allegations of the Complaint and seeking damages on its Counterclaim, in an amount to be determined at trial, for intentional overbilling by FTI. On February 7, 2017, a preliminary conference was held by the Court at which time a scheduling order governing discovery was issued. On June 26, 2017, the Company and FTI entered into a settlement agreement.

According to FTI, as of June 2017, FTI was owed \$862,165 including interest charges and legal fees. Under the terms of the settlement agreement, the Company paid an aggregate of \$435,000 to FTI on June 30, 2017.

#### Sinotau Litigation – Tc99m Tilmanocept

On February 1, 2017, Navidea filed suit against Sinotau in the U.S. District Court for the Southern District of Ohio. The Company's complaint included claims seeking a declaration of the rights and obligations of the parties to an agreement regarding rights for the Tc99m tilmanocept product in China and other claims. The complaint sought a temporary restraining order ("TRO") and preliminary injunction to prevent Sinotau from interfering with the Company's Asset Sale to Cardinal Health 414. On February 3, 2017, the Court granted the TRO and extended it until March 6, 2017. The Asset Sale closed on March 3, 2017. On March 6, the Court dissolved the TRO as moot. Sinotau also filed a suit against the Company and Cardinal Health 414 in the U.S. District Court for the District of Delaware on February 2, 2017. On July 12, 2017, the District of Delaware case was transferred to the Southern District of Ohio. On July 27, 2017 the Ohio Court determined that both cases in the Southern District of Ohio are related and the case was stayed for 60 days pending settlement discussions. On February 8, 2018, Navidea and Sinotau executed an amendment to the agreement, modifying certain terms of the agreement and effectively resolving the legal dispute. On February 17, 2018, Navidea and Sinotau executed a Settlement Agreement and Mutual Release, and on February 20, 2018, Navidea and Sinotau voluntarily dismissed their legal cases.

## Platinum-Montaur Life Sciences LLC

On November 2, 2017, Platinum-Montaur Life Sciences LLC ("Platinum-Montaur") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of \$1,914,827.22 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement (discussed below). Said action was removed to the United States District of New York on December 6, 2017. An initial pretrial conference was held on January 26, 2018. At the conference the Court stayed the deadline for the Company to answer or otherwise respond to the complaint. The Court also directed the parties to engage in informal jurisdictional discovery and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss is due on April 6, 2018. The Court also referred the case to a settlement conference, which has been scheduled for April 30, 2018. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

## 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." Prior to our name change from Neoprobe Corporation to Navidea Biopharmaceuticals, Inc. on January 5, 2012, our common stock was traded on the NYSE American under the trading symbol NEOP. The prices set forth below reflect the quarterly high and low sales prices for shares of our common stock during the last two fiscal years.

	High		Low		
Fiscal Year 2017:					
First Quarter	\$	0.85	\$	0.29	
Second Quarter		0.62		0.43	
Third Quarter		0.51		0.37	
Fourth Quarter		0.68		0.35	
Fiscal Year 2016:					
First Quarter	\$	1.35	\$	0.75	
Second Quarter		1.51		0.51	
Third Quarter		1.14		0.26	
Fourth Quarter		1.16		0.57	

As of March 1, 2018, we had approximately 600 holders of common stock of record.

We have not paid any dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. We intend to retain any earnings to finance the growth of our business and we may never pay cash dividends. Whether we pay cash dividends in the future will be at the discretion of our Board of Directors and will depend upon our financial condition, results of operations, capital requirements and any other factors that the Board of Directors decides are relevant. See Management's Discussion and Analysis of Financial Condition and Results of Operations.

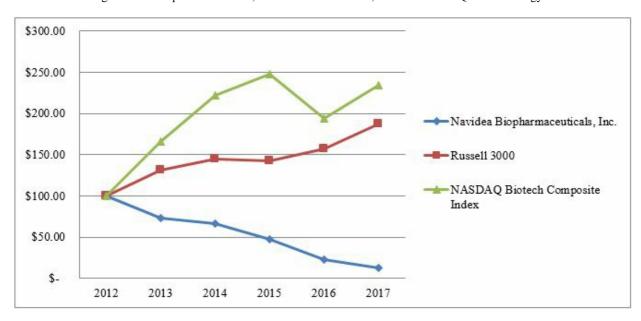
There were no repurchases of our common stock during the three-month period ended December 31, 2017.

#### **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, 2012 through December 31, 2017. This graph assumes an investment in the Company's common stock and the indices of \$100 on December 31, 2012 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 12/31/2012 in stock or index, including reinvestment of dividends.

Cumulative	Total	Return	as	of	December 3	1,

	 2012	2013		2014		2015		2016			2017
Navidea Biopharmaceuticals	\$ 100.00	\$	73.14	\$	66.78	\$	47.00	\$	22.61	\$	12.72
Russell 3000	100.00		130.95		144.63		142.50		157.34		187.01
NASDAQ Biotechnology	100.00		165.61		222.08		247.44		193.79		234.60

#### Item 6. Selected Financial Data

The following summary financial data are derived from our consolidated financial statements that have been audited by our independent registered public accounting firms. These data are qualified in their entirety by, and should be read in conjunction with, our Consolidated Financial Statements and Notes thereto included elsewhere in this Form 10-K as well as Management's Discussion and Analysis of Financial Condition and Results of Operations.

On March 3, 2017, Navidea completed the sale to Cardinal Health 414 of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer, including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the FDA and similar indications approved by the FDA in the future, in Canada, Mexico and the United States. As a result of the Asset Sale, the Company's consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the Business as a discontinued operation.

Summary financial data for 2013 to 2015 also reflect the disposition of our gamma detection device business in August 2011 and the reclassification of certain related items to discontinued operations.

(Amounts in thousands, except per share data)	Years Ended December 31,									
										2013
		2017		2016		2015		2014	<u>(</u> 1	inaudited)
Statement of Operations Data:										
Revenue	\$	1,810	\$	4,972	\$	3,013	\$	2,054	\$	523
Cost of goods sold		4		62		3		3		1
Research and development expenses		4,513		7,138		10,563		15,117		17,659
Selling, general and administrative expenses		11,170		7,920		10,888		9,526		10,578
Loss from operations		(13,877)		(10,149)		(18,441)		(22,591)		(27,715)
Other income (expense), net		(3,913)		2,771		(4,604)		(7,767)		(3,792)
Benefit from income taxes		4,062		<u> </u>		436				
Loss from continuing operations		(13,727)		(7,378)		(22,609)		(30,359)		(31,508)
Discontinued operations, net of tax effect		88,673		(6,931)		(4,955)		(5,368)		(11,192)
Net income (loss)		74,946		(14,309)		(27,564)		(35,727)		(42,699)
Less loss attributable to noncontrolling interest		_		(1)		(1)		_		_
Deemed dividend				<u> </u>		(46)				
Income (loss) attributable to common stockholders	\$	74,946	\$	(14,308)	\$	(27,609)	\$	(35,727)	\$	(42,699)
Income (loss) per common share (basic):										
Continuing operations	\$	(0.08)	\$	(0.05)	\$	(0.15)	\$	(0.20)	\$	(0.26)
Discontinued operations	\$	0.55	\$	(0.04)	\$	(0.03)	\$	(0.04)	\$	(0.09)
Income (loss) attributable to common stockholders	\$	0.47	\$	(0.09)	\$	(0.18)	\$	(0.24)	\$	(0.35)
Weighted average shares outstanding (basic) <sup>1</sup>		161,593		155,422		151,180		148,748		121,809
Income (loss) per common share (diluted):										
Continuing operations	\$	(0.08)	\$	(0.05)	\$	(0.15)	\$	(0.20)	\$	(0.26)
Discontinued operations	\$	0.53	\$	(0.04)	\$	(0.03)	\$	(0.04)	\$	(0.09)
Income (loss) attributable to common stockholders	\$	0.45	\$	(0.09)	\$	(0.18)	\$	(0.24)	\$	(0.35)
Weighted average shares outstanding (diluted) <sup>2</sup>		166,016		155,422		151,180		148,748		121,809

	 115 of December 51,								
	2017		2016		2015		2014		2013 naudited)
Balance Sheet Data:									
Total assets	\$ 20,781	\$	12,462	\$	14,965	\$	11,830	\$	39,626
Long-term liabilities	665		10,266		62,616		32,573		32,703
Accumulated deficit	(319,909)		(394,855)		(380,547)		(352,984)		(317,257)

As of December 31.

<sup>(1)</sup> Basic earnings (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares and, except for periods with a loss from operations, participating securities outstanding during the period.

Diluted earnings (loss) per share reflects additional common shares that would have been outstanding if dilutive potential common shares had been issued. Potential common shares that may be issued by the Company include convertible securities, convertible debt, options and warrants.

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

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

#### The Company

Navidea Biopharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on our Manocept platform to enhance patient care by identifying the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and targeted treatment.

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc99m tilmanocept, the first product developed by Navidea based on the platform.

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

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

Other than 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.

## **Executive Summary**

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.

The flexible and versatile Manocept acts as a platform molecular engine for the design of targeted imaging molecules applicable to a range of diagnostic modalities, including SPECT, PET, gamma-scanning (both imaging and topical) and intra-operative and/or optical-fluorescence detection. Active clinical diagnostic programs in several diseases (discussed below) representing specific macrophage activation states are ongoing.

Cardiovascular Disease – A nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc99m tilmanocept product dosed subcutaneously was completed (ClinicalTrials.gov NCT02542371). The results of this study were presented at two major international meetings (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 AIDS patients (supported by NIH/NHLBI Grant 1 R43 HL127846-01). We have also begun a second Phase1/2 study in cooperation with Massachusetts General Hospital. This study expands the initial investigation to the assessment of not only aortic plaque but also carotid and coronary arteries. In addition, we have applied for follow-on NIH/NHLBI support to fund additional clinical studies. These studies are currently under development and design for Phase 2 trials.

Rheumatoid Arthritis – Two Tc99m tilmanocept dose escalation studies in RA have been initiated. The first study, now complete (ClinicalTrials.gov NCT02683421), included 18 subjects (9 with active disease and 9 healthy subjects) dosed subcutaneously with 50 and 200 µg/2mCi Tc99m tilmanocept. The results of this study were presented at three international meetings, including BIO, SNMMI, and ACR, 2017. This study is submitted for peer review publication. In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have completed a study involving IV dosing of Tc99m tilmanocept (ClinicalTrials.gov NCT02865434). In conjunction with this study, we have completed PK and PD phases in human subjects as well. The majority of the studies have been supported through a SBIR grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1). We anticipate a presentation of the results at the 2018 SNMMI meeting and full published results thereafter.

Kaposi's Sarcoma – Although we initiated and completed a study of KS in 2015 (ClinicalTrials.gov NCT022201420), we received additional funding from the NIH in 2016 to continue both diagnostic and therapeutic 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). Additionally, we received funding to support the therapeutic initiative for KS employing a select form of the MT-1001.3 agent under current evaluation. The Company has already completed a portion of the Phase 1 SBIR portion of this award (NIH/NCI 1 R44 CA206788-01) and will complete Phase 2 of the award with FDA IND filing.

Colorectal Cancer and Synchronous Liver Metastases – During the first quarter of 2017, we initiated an imaging study in subjects with CRC and liver metastases via IV administration of Tc99m tilmanocept. This study has results but will continue to enroll subjects (up to 12 subjects with dose modification; this study may also be expanded depending on NIH/NCI funding). This study is supported through a SBIR grant (NIH/NCI 1 R44 CA1962783-01A1; ClinicalTrials.gov NCT03029988).

Nonalcoholic Steatosis Hepatitis – Navidea has initiated a study in the imaging of NASH. This study (ClinicalTrials.gov NCT03332940) is designed to enroll 12 subjects with IV administration of Tc99m tilmanocept and an imaging comparator, and includes dose escalation modification for Tc99m tilmanocept. This study is ongoing and has results which will be reported later in the year.

Based on performance in these very large imaging market opportunities the Company anticipates continued investment in these programs including initiating studies designed to obtain new approvals for the Tc99m tilmanocept product.

The Company has completed further preclinical studies employing both MT 1000-class and 2000-class therapeutic conjugates of Manocept. The highly positive results from these studies are indicative of Manocept's specific targeting supported by its notable binding affinity to CD206 receptors. This high 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 CNS diseases. Our efforts in this area were further supported by the 2015 formation of MT, a majority-owned subsidiary that was formed specifically to explore therapeutic applications for the Manocept platform. Results of these preclinical efforts will be published later this year pending the conclusion of intellectual property applications.

MT has been set up to pursue the therapeutic drug delivery model. This model enables the Company to leverage its technology over many potential disease applications and with multiple partners simultaneously without significant capital outlays. To date, the Company has developed two lead families of therapeutic products. The MT-1000 class is designed to deplete activated macrophages via apoptosis. The MT-2000 class is designed to modulate activated macrophages from a classically activated phenotype to the alternatively activated phenotype. Both families have been tested in a number of disease models in rodents.

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

In the near term, the Company intends to continue to 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 Tc99m tilmanocept, our Manocept platform, and NAV4694 and NAV5001 product development. We incurred approximately \$4.5 million, \$7.1 million and \$10.6 million in total on research and development activities during the years ended December 31, 2017, 2016 and 2015, 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 <sup>(a)</sup>	 2017	2016	 2015
Tc99m tilmanocept	\$ 359,398	\$ 2,002,449	\$ 2,365,128
Manocept platform	2,329,586	1,045,102	767,431
Macrophage Therapeutics	652,947	679,961	538,813
NAV4694 <sup>(b)</sup>	(371,588)	1,590,607	3,448,724
NAV5001 <sup>(b)</sup>	(91,336)	97,602	385,344

- (a) Amounts reflect projects included in discontinued operations in the consolidated statements of operations. Certain development program expenditures were offset by grant reimbursement revenues totaling \$1.7 million, \$2.8 million, and \$1.7 million during the years ended December 31, 2017, 2016 and 2015, respectively.
- (b) Changes in cost estimates resulted in the reversal of certain previously accrued expenses related to the NAV4694 and NAV5001 development programs during the year ended December 31, 2017.

We expect to continue the advancement of our efforts with our Manocept platform during 2018. The divestiture of NAV5001 and the suspension of active patient accrual in our NAV4694 trials have decreased our development costs over the past year. We expect our total research and development expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be higher in 2018 than in 2017.

Tc99m tilmanocept is approved by the EMA for use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity in the EU. Following the January 2017 transfer of the Tc99m tilmanocept Marketing Authorization to SpePharm, we transferred responsibility for manufacturing the reduced-mass vial for the EU market to SpePharm. During the second quarter of 2017, SpePharm launched Tc99m tilmanocept in select EU markets, providing a number of early adopters with sample doses to provide exposure to the product. EU sales commenced during the third quarter of 2017. We anticipate that we will incur costs related to supporting our product, regulatory, manufacturing and commercial activities related to the potential marketing registration and sale of Tc99m tilmanocept in markets other than the EU. There can be no assurance that Tc99m tilmanocept will achieve regulatory approval in any market other than the EU, or if approved in those markets, that it will achieve market acceptance in the EU or any other market. See Risk Factors.

We are currently evaluating existing and emerging data on the potential use of Manocept-related agents in the diagnosis and disease-staging of disorders in which macrophages are involved, such as KS, RA, vulnerable plaque/atherosclerosis, TB and other disease states, to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform. We will also be evaluating potential funding and other resources required for continued development, regulatory approval and commercialization of any Manocept platform product candidates that we identify for further development, and potential options for advancing development. There can be no assurance that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance. See Risk Factors.

## **Discontinued Operations**

In March 2017, Navidea completed the Asset Sale to Cardinal Health 414, as discussed previously under "Development of the Business." In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately \$80.6 million after adjustments based on inventory being transferred and an advance of \$3.0 million of guaranteed earnout payments as part of the CRG settlement, (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3.0 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG.

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

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

## **Results of Operations**

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

Tc99m Tilmanocept License Revenue. During 2017, we recognized license revenue of \$100,000 for a non-refundable upfront payment related to the Tc99m tilmanocept license and distribution agreement with Sayre Therapeutics in India. During 2016, we recognized \$1.2 million of the \$2.0 million non-refundable upfront payment received by the Company related to the Tc99m tilmanocept license and distribution agreement for Europe. The Company had been recognizing this revenue on a straight-line basis over two years, however the remaining deferred revenue of \$417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, five months earlier than originally anticipated. During 2016, we also recognized \$500,000 of milestone revenue upon obtaining European approval of the reduced-mass vial, as well as \$127,000 reimbursement of certain clinical development costs, in accordance with the terms of the Tc99m tilmanocept distribution agreement for Europe.

Grant and Other Revenue. During 2017, we recognized \$1.7 million of grant and other revenue as compared to \$3.1 million in 2016. Grant revenue during 2017 was primarily related to SBIR grants from the NIH supporting Manocept, Tc99m tilmanocept and therapeutic development. Grant revenue during 2016 was primarily related to SBIR grants from the NIH supporting Manocept, Tc99m tilmanocept, NAV4694 and therapeutic development. Other revenue for 2017 and 2016 included \$31,000 and \$258,000, respectively, of revenue from our marketing partners in Europe and China related to development work performed at their request. Other revenue for 2016 also included \$33,000 related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased \$2.6 million, or 37%, to \$4.5 million during 2017 from \$7.1 million during 2016. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of \$2.0 million including decreased manufacturing-related activities, clinical trial costs and licensing costs, while we continued our efforts to divest the program; (ii) decreased Tc99m tilmanocept development costs of \$1.4 million including decreased manufacturing-related activities, regulatory costs, clinical trial costs and licensing costs; and (iii) decreased NAV5001 development costs of \$189,000 including decreased clinical trial costs and manufacturing-related activities; offset by (iv) increased Manocept platform development costs of \$1.4 million including increased clinical trial costs and licensing costs. The net decrease in research and development expenses also included decreased compensation including incentive-based awards and other expenses related to net decreased headcount of \$467,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$3.3 million, or 41%, to \$11.2 million during 2017 from \$7.9 million during 2016. The net increase was primarily due to increased compensation costs of \$1.3 million including incentive-based awards and termination costs related to the arbitration award to Mr. Gonzalez, increased legal and professional services of \$1.0 million, a loss on disposal of assets primarily related to our previous office space of \$996,000 and a loss on termination of our previous office lease of \$399,000.

Other Income (Expense). Other expense, net, was \$3.9 million during 2017 compared to other income, net of \$2.8 million during 2016. We recorded a loss on extinguishment of the CRG debt of \$4.2 million during 2017. Also during 2017, we recognized interest income of \$328,000 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. During 2017, \$265,000 of interest expense was compounded and added to the balance of our note payable to Platinum. During 2017 and 2016, we recorded non-cash income of \$153,000 and \$2.9 million, respectively, related to changes in the estimated fair value of financial instruments. During 2016, we recorded a non-cash loss on the disposal of our investment in R-NAV, LLC ("R-NAV") of \$40,000.

Gain on Discontinued Operations. We recorded a net gain on the sale of the Business to Cardinal Health 414 of \$89.2 million in 2017, including \$16.5 million in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by \$3.3 million in estimated fair value of warrants issued to Cardinal Health 414, \$2.0 million in legal and other fees related to the sale, \$800,000 in net balance sheet dispositions and write-offs, and \$4.1 million in estimated taxes. Operating losses from discontinued operations related to the sale of the Business to Cardinal Health 414 were \$491,000 and \$6.9 million for 2017 and 2016, respectively.

Years Ended December 31, 2016 and 2015

Tc99m Tilmanocept License Revenue. During 2016 and 2015, we recognized \$1.2 million and \$833,000, respectively, of the \$2.0 million non-refundable upfront payment received by the Company related to the Tc99m tilmanocept license and distribution agreement for Europe. The Company had been recognizing this revenue on a straight-line basis over two years, however the remaining deferred revenue of \$417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, five months earlier than originally anticipated. During 2016, we also recognized \$500,000 of milestone revenue upon obtaining European approval of the reduced-mass vial, as well as \$127,000 reimbursement of certain clinical development costs, in accordance with the terms of the Tc99m tilmanocept distribution agreement for Europe. During 2015, we recognized \$300,000 of Tc99m tilmanocept license revenue from a non-refundable milestone payment received by the Company related to the Tc99m tilmanocept distribution agreement for China, for which the Company has no future obligations.

Grant and Other Revenue. During 2016, we recognized \$3.1 million of grant and other revenue as compared to \$1.9 million in 2015. Grant revenue during 2016 was primarily related to SBIR grants from the NIH supporting Manocept, Tc99m tilmanocept, NAV4694 and therapeutic development. Grant revenue during 2015 was primarily related to SBIR grants from the NIH supporting NAV4694, Tc99m tilmanocept and Manocept development. Grant and other revenue during 2016 included \$173,000 from sales of non-commercial product to our European distribution partner. Grant and other revenue for 2016 and 2015 also included \$33,000 and \$140,000, respectively, related to services provided to R-NAV for Manocept development.

Research and Development Expenses. Research and development expenses decreased \$3.4 million, or 32%, to \$7.1 million during 2016 from \$10.5 million during 2015. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of \$1.9 million including decreased clinical trial costs and manufacturing-related activities offset by increased licensing costs, while we continued our efforts to divest the program; (ii) decreased Tc99m tilmanocept development costs of \$364,000 including decreased manufacturing-related activities and pre-clinical testing, offset by increased licensing, clinical trial and regulatory costs; and (iii) decreased NAV5001 development costs of \$288,000 including decreased manufacturing-related activities and clinical trial costs; offset by (iv) increased Manocept platform development costs of \$278,000 including increased clinical trial costs offset by decreased preclinical testing, license fees and manufacturing-related activities; and (v) increased therapeutics development costs of \$141,000 including increased consulting costs offset by decreased scientific advisory board fees and manufacturing-related activities. The net decrease in research and development expenses also included decreased compensation including incentive-based awards and other expenses related to net decreased headcount of \$1.3 million following the first quarter 2015 reduction in force.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased \$3.0 million, or 27%, to \$7.9 million during 2016 from \$10.9 million during 2015. The net decrease was primarily due to decreased general and administrative headcount of \$2.2 million following the first quarter 2015 reduction in force coupled with decreased travel, office and other support costs of \$795,000, consulting services of \$671,000, and investor relations of \$212,000, offset by increased legal and professional services of \$879,000.

Other Income (Expense). Other income, net, was \$2.8 million during 2016 as compared to other expense, net of \$4.6 million during 2015. Interest expense, net decreased \$1.3 million to \$5,000 during 2016 from \$1.3 million for 2015, primarily due to outstanding balance of the Oxford Notes in 2015. Of this interest expense, \$326,000 in 2015 was non-cash in nature related to the amortization of debt issuance costs and debt discounts related to the Oxford Notes. For 2016 and 2015, we recorded non-cash income (expense) of \$2.9 million and (\$615,000), respectively, related to changes in the estimated fair value of financial instruments. During 2016 and 2015, we recorded non-cash equity in the loss of R-NAV of \$15,000 and \$305,000, respectively. During 2016, we also recorded a non-cash loss on the disposal of our investment in R-NAV of \$40,000. During 2015, we recorded \$2.4 million of losses on the extinguishment of the Oxford Notes.

Loss from Discontinued Operations. Loss from discontinued operations was \$6.9 million during 2016 as compared to \$4.5 million in 2015. Loss from discontinued operations included operating losses related to the sale of the Business to Cardinal Health 414 of \$6.9 million and \$5.7 million for 2016 and 2015, respectively. During 2015, we also recorded net income from the sale of the GDS Business to Devicor of \$759,000 related to royalty amounts earned based on 2015 GDS Business revenue. The royalty amount of \$1.2 million was offset by \$436,000 in estimated taxes which were allocated to discontinued operations, but were fully offset by the tax benefit from our net operating loss for 2015.

# **Liquidity and Capital Resources**

Cash balances increased to \$2.8 million at December 31, 2017 from \$1.5 million at December 31, 2016. The net increase was primarily due to net cash received for the Asset Sale to Cardinal Health 414, offset by payments made on the CRG and Platinum debts and investments in available-for-sale securities coupled with cash used to fund our operations.

All of our material assets were pledged as collateral for our borrowings under the CRG Loan Agreement. In addition to the security interest in our assets, the CRG Loan Agreement carried covenants that imposed significant requirements on us. An event of default entitled CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

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

The trial was held in Texas in December 2017. The Texas Court ruled that the Company's total obligation to CRG is 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 owes 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. The Company believes that this \$4.1 million should be credited against the \$7 million; CRG disagrees. On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the Texas Court's oversight of not explaining how to apply the \$4.1 million payment, requesting that the judgment be modified to set the supersedeas amount at \$2.9 million so that the Company can stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. The Texas Court has scheduled a hearing on the issue for March 26, 2018, however it has not yet set the amount, and enforcement of the judgment is stayed until seven days after the Texas Court does so. We currently await further action by the Texas Court. If we are ultimately required to pay an additional \$7.0 million to CRG, such payment would have a significant adverse effect on our financial position and would likely force us to curtail our planned development activities.

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to Platinum Partners Capital Opportunity Fund L.P. ("PPCO") an aggregate of approximately \$7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which were transferred by Platinum-Montaur to PPCO. The Company was informed by Platinum Partners Value Arbitrage Fund L.P. ("PPVA") that it was the owner of additional amounts owed on the Platinum-Montaur loan. PPVA claims a balance of approximately \$1.9 million was due upon closing of the Asset Sale. That amount is also subject to competing claims of ownership by Dr. Michael Goldberg, the Company's President and Chief Executive Officer. The Company has not yet paid the balance to anyone, as ownership is subject to dispute.

On March 2, 2017, PPCO provided a payoff letter (the "Payoff Letter"). In the Payoff Letter, PPCO defined "Indebtedness" to include all amounts due under the Platinum Note, indicated that upon payment of the Payoff Amount, all "Indebtedness owed to Lender" shall have been satisfied in full, and that the "Loan Documents," which included the Platinum Loan Agreement and the Platinum Note, "shall terminate and have no further force or effect." The letter also confirmed that as of the date that payment was made by Navidea, the Receiver was providing a release and indemnification in favor of Navidea based on any claims made by any affiliate of PPCO. The Payoff Amount was paid pursuant to the Payoff Letter.

The remaining balance of the Platinum Note would have matured under its terms in September 2017, however the Company has not paid the balance as it is still subject to ongoing competing claims of ownership. The Company intends to pay the balance of the debt if it is determined to be due and owing to PPVA or Dr. Goldberg.

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of \$1,914,827.22 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement. Said action was removed to the United States District of New York on December 6, 2017. An initial pretrial conference was held on January 26, 2018. At the conference the Court stayed the deadline for the Company to answer or otherwise respond to the complaint. The Court also directed the parties to engage in informal jurisdictional discovery and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss is due on April 6, 2018. The Court also referred the case to a settlement conference, which has been scheduled for April 30, 2018. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

As of December 31, 2017, the outstanding principal balance of the Platinum Note was approximately \$2.0 million.

Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern was alleviated. Based on our current working capital and our projected cash burn, including our belief that the Company will be obligated to pay up to an additional \$2.9 million to CRG, management believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Annual Report on Form 10-K. Our projected cash burn also factors in certain cost cutting initiatives that have been implemented and approved by the board of directors, including reductions in the workforce and a reduction in facilities expenses. Additionally, we have considerable discretion over the extent of development project expenditures and have the ability to curtail the related cash flows as needed. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of non-dilutive funding, including collaborations and additional grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be supported by our revenues. We believe all of these factors are sufficient to alleviate substantial doubt about the Company's ability to continue as a going concern.

Operating Activities. Cash provided by operations was \$59.1 million during 2017 compared to \$3.6 million provided during 2016.

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

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

Accounts and other receivables increased to \$8.1 million at December 31, 2017 from \$203,000 at December 31, 2016, primarily related to the current portion of the guaranteed earnout due from Cardinal Health 414, which was discounted and recorded at present value. The change in accounts and other receivables also reflects a decrease in receivables from our European distribution partner.

Inventory levels decreased to \$0 at December 31, 2017 from \$96,000 at December 31, 2016, primarily due to the use of materials for European manufacturing development and production. We expect inventory levels to remain minimal during 2018 as European manufacturing has been transitioned to our distribution partner and sales in India, China and other international markets are not expected to be significant.

Prepaid expenses and other current assets increased to \$1.1 million at December 31, 2017 from \$842,000 at December 31, 2016, primarily due to increased taxes receivable, prepaid insurance, investor relations and other services coupled with increased interest receivable related to the guaranteed earnout due from Cardinal Health 414, offset by decreased legal retainers and amortization of prepaid services.

Accounts payable decreased to \$855,000 at December 31, 2017 from \$5.2 million at December 31, 2016, primarily driven by net decreased payables due for NAV4694, legal and professional services, Tc99m tilmanocept European manufacturing, regulatory and operations vendors. Accrued liabilities and other current liabilities decreased to \$1.9 million at December 31, 2017 from \$7.9 million at December 31, 2016, primarily driven by decreased accruals for interest, NAV4694, therapeutic development and general operations costs, offset by increased accruals for Manocept development costs. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we resolve legal disputes and continue to decrease our level of development activity related to NAV4694, offset by planned increases in development activity related to the Manocept platform.

Assets associated with discontinued operations decreased to \$0 at December 31, 2017 from \$3.2 million at December 31, 2016, and liabilities associated with discontinued operations decreased to \$7,000 at December 31, 2017 from \$4.9 million at December 31, 2016. Decreases in both assets and liabilities associated with discontinued operations were primarily due to the Asset Sale to Cardinal Health 414 in March 2017.

Investing Activities. Investing activities used \$1.8 million during 2017 compared to using \$39,000 in 2016. Investing activities during 2017 included purchases of available-for-sale securities of \$2.2 million and capital expenditures of \$34,000, primarily for computer equipment and leasehold improvements, offset by maturities of available-for-sale securities of \$400,000. Investing activities during 2016 included net payments related to the disposal of our investment in R-NAV of \$82,000 and capital expenditures of \$2,000, primarily for computer equipment, offset by proceeds from sales of capital equipment of \$45,000. We expect our overall capital expenditures for 2018 will be somewhat less than 2017 as we maintain our technology infrastructure.

Financing Activities. Financing activities used \$56.0 million during 2017 compared to using \$9.1 million in 2016. The \$56.0 million used by financing activities in 2017 consisted primarily of principal payments on the CRG, Platinum and IPFS notes payable of \$59.8 million, offset by the release of restricted cash of \$5.0 million and proceeds from issuance of common stock of \$72,000. The \$9.1 million used by financing activities in 2016 consisted primarily of restrictions placed on cash in an account controlled by CRG of \$5.0 million, payment of debt-related costs of \$3.9 million, and principal payments on notes payable of \$231,000, primarily related to the CRG debt.

Investment in Macrophage Therapeutics, Inc.

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

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

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

In July 2016, MT's Board of Directors authorized modification of the original investments of \$300,000 by Platinum and \$200,000 by Dr. Goldberg to a convertible preferred stock with a 10% PIK coupon retroactive to the time the initial investments were made. The conversion price of the preferred will remain at the \$500 million initial market cap but a full ratchet will be added to enable the adjustment of conversion price, warrant number and exercise price based on the valuation of the first institutional investment round. In addition, the MT Board authorized issuance of additional convertible preferred stock with the same terms to Platinum as compensation for the additional \$200,000 of investments made in December 2015 and May 2016. Based on the MT Board's authorization of additional equity, the Company reclassified the additional \$200,000 from a current liability to equity during the year ended December 31, 2017. 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.

## Capital Royalty Partners II, L.P. Debt

Prior to the Asset Sale to Cardinal Health 414 in March 2017, all of our material assets were pledged as collateral for our borrowings under the Term Loan Agreement (the "CRG Loan Agreement") with CRG. In addition to the security interest in our assets, the CRG Loan Agreement included covenants that imposed significant requirements on us. An event of default would have entitled CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement. During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of \$4.1 million that was on deposit. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

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

The trial was held in Texas in December 2017. The Texas Court ruled that the Company's total obligation to CRG is 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 owes 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. The Company believes that this \$4.1 million should be credited against the \$7 million; CRG disagrees. On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the Texas Court's oversight of not explaining how to apply the \$4.1 million payment, requesting that the judgment be modified to set the supersedeas amount at \$2.9 million so that the Company can stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. The Texas Court has scheduled a hearing on the issue for March 26, 2018, however it has not yet set the amount, and enforcement of the judgment is stayed until seven days after the Texas Court does so. We currently await further action by the Texas Court. If we are ultimately required to pay an additional \$7.0 million to CRG, such payment would have a significant adverse effect on our financial position and would likely force us to curtail our planned development activities.

## Platinum Credit Facility

The Platinum Loan Agreement, as amended, provided us with a credit facility of up to \$50 million. We drew a total of \$4.5 million under the credit facility during the year ended December 31, 2015. We did not make any draws under the credit facility during the years ended December 31, 2016 and 2014. The credit facility bore interest at the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10.0%; or (c) the highest rate of interest then payable pursuant to the CRG Term Loan plus 0.125%, compounded monthly. In accordance with the terms of a Section 16(b) Settlement Agreement, Platinum agreed to forgive interest owed on the credit facility in an amount equal to 6%, effective July 1, 2016. As of December 31, 2017, the effective interest rate was 8.125%. Platinum had the right, at Platinum's option subject to certain conditions, to convert all principal and interest outstanding under the Platinum Loan Agreement (the "Conversion Amount") into shares of the Company's common stock, but not until such time as the average daily volume weighted average price of the Company's common stock for the ten preceding trading days exceeded \$2.53 per share. Following the maturity of the Platinum Loan Agreement in September 2017, Platinum no longer has any rights to convert.

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. The Company was informed by PPVA that it was the owner of additional amounts owed on the Platinum-Montaur loan. PPVA claims a balance of approximately \$1.9 million was due upon closing of the Asset Sale. That amount is also subject to competing claims of ownership by Dr. Michael Goldberg, the Company's President and Chief Executive Officer. The Company has not yet paid the balance to anyone, as ownership is subject to dispute.

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of \$1,914,827.22 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement. Said action was removed to the United States District of New York on December 6, 2017. An initial pretrial conference was held on January 26, 2018. At the conference the Court stayed the deadline for the Company to answer or otherwise respond to the complaint. The Court also directed the parties to engage in informal jurisdictional discovery and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss is due on April 6, 2018. The Court also referred the case to a settlement conference, which has been scheduled for April 30, 2018. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

During the years ended December 31, 2017, 2016 and 2015, \$265,000, \$1.0 million and \$761,000 of interest was compounded and added to the balance of the Platinum Note, respectively. As of December 31, 2017, the remaining outstanding principal balance of the Platinum Note was approximately \$2.0 million.

# Cardinal Health 414 Asset Sale

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

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

Upon closing of the Asset Sale, the Supply and Distribution Agreement between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect. The completion of the Asset Sale significantly improved our financial condition and our ability to continue as a going concern.

#### Summary

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

We plan to focus our resources for 2018 primarily on development of products based on the Manocept platform. Although management believes that it will be able to achieve these objectives, they are subject to a number of variables beyond our control, including the outcome of the remaining CRG litigation, the nature and timing of any partnering opportunities, the ability to modify contractual commitments made in connection with these programs, and the timing and expense associated with suspension or alteration of clinical trials, and consequently there can be no assurance that we will be able to achieve our objective of bringing our expenses in line with our revenues, and we may need to seek additional debt or equity financing if we cannot achieve that objective in a timely manner.

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

Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern was alleviated. Based on our current working capital and our projected cash burn, including our belief that the Company will be obligated to pay up to an additional \$2.9 million to CRG, management believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Annual Report on Form 10-K. Our projected cash burn also factors in certain cost cutting initiatives that have been implemented and approved by the board of directors, including reductions in the workforce and a reduction in facilities expenses. Additionally, we have considerable discretion over the extent of development project expenditures and have the ability to curtail the related cash flows as needed. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of non-dilutive funding, including collaborations and additional grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be supported by our revenues. We believe all of these factors are sufficient to alleviate substantial doubt about the Company's ability to continue as a going concern.

We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. There can be no assurance that if we attempt to raise additional capital through debt, royalty, equity or otherwise, we will be successful in doing so on terms acceptable to the Company, or at all. Further, there can be no assurance that we will be able to gain access and/or be able to execute on securing new sources of funding, new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future. See Risk Factors.

# **Off-Balance Sheet Arrangements**

As of December 31, 2017, we had no off-balance sheet arrangements.

# **Recent Accounting Standards**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is that a company should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five-step process that requires companies to exercise more judgment and make more estimates than under the current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. Since the issuance of ASU 2014-09, several additional ASUs have been issued and incorporated within Topic 606 to clarify various elements of the guidance. ASU 2014-09 allows a choice of transition methods: (a) a full retrospective adoption in which the standard is applied to all of the periods presented, or (b) a modified retrospective adoption in which the standard is applied only to the most current period presented in the financial statements with a cumulative-effect adjustment reflected in retained earnings. ASU 2014-09 also requires significantly expanded disclosures regarding the qualitative and quantitative information of an entity's nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those periods.

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

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

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

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

Following the sale of the Business to Cardinal Health 414 in March 2017, we generate revenue primarily from grants to support certain of our product development programs. Such grant revenues are recognized only after expenses reimbursable under the grants have been paid. 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 will require separate assessment using the five-step process under ASU 2014-09. We adopted ASU 2014-09 along with additional related ASUs 2016-08, 2016-10, 2016-12 and 2016-20 effective January 1, 2018 using the modified retrospective method of adoption. The Company expects the adoption of ASU 2014-09 and related ASUs to result in increases in deferred revenue and accumulated deficit of approximately \$100,000.

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

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

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows – Restricted Cash*. ASU 2016-18 requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash or equivalents. Therefore, restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption in permitted, including adoption in an interim period. If an entity early adopts ASU 2016-18 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes the interim period. We adopted ASU 2016-18 effective January 1, 2018. The Company expects the adoption of ASU 2016-18 to result in reclassification of \$5.0 million of restricted cash in the consolidated statement of cash flows for the years ended December 31, 2017 and 2016.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business.* ASU 2017-01 provides a screen to determine when a set of assets and activities (collectively, a "set") is not a business. The screen requires that when substantially all of the fair market value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, ASU 2017-01 (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output, and (2) removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those periods. ASU 2017-01 should be applied prospectively on or after the effective date. No disclosures are required at transition. Early adoption is permitted for certain transactions as described in ASU 2017-01. The adoption of ASU 2017-01 effective January 1, 2018 did not have a material effect on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting.* ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all of the following criteria are met: (1) The fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification. (2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified. (3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. Disclosure requirements remain unchanged. ASU 2017-09 is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted as described in ASU 2017-09. The adoption of ASU 2017-09 effective January 1, 2018 did not have a material effect on our consolidated financial statements.

In September 2017, the FASB issued ASU No. 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842). ASU 2017-13 adds SEC paragraphs pursuant to an SEC Staff Announcement made in July 2017 and clarifies several issues related to transition and implementation of the covered topics, including clarification of the definition of a public business entity, the effect of a change in tax law or rates on leveraged leases, and related amendments to the eXtensible Business Reporting Language ("XBRL") taxonomy. Management is currently evaluating the impact that the adoption of ASU 2017-13 will have on our 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 earn additional revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

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

*Use of Estimates*. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base these estimates and assumptions upon historical experience and existing, known circumstances. Actual results could differ from those estimates. Specifically, management may make significant estimates in the following areas:

• Stock-Based Compensation. Stock-based payments to employees and directors, including grants of stock options and restricted stock, are recognized in the statements of operations based on their estimated fair values on the date of grant, subject to an estimated forfeiture rate. The fair value of each option award with time-based vesting provisions is estimated on the date of grant using the Black-Scholes option pricing model to value such stock-based payments and the portion that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. The determination of fair value using the Black-Scholes option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option behaviors. The fair value of each option award with market-based vesting provisions is estimated on the date of grant using a Monte Carlo simulation to value such stock-based payments and the portion that is ultimately expected to vest is recognized as compensation expense over either (1) the requisite service period or (2) the estimated performance period. The determination of fair value using a Monte Carlo simulation is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option behaviors.

We estimate the expected term based on the contractual term of the awards and employees' exercise and expected post-vesting termination behavior. Restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award.

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

- Fair Value of Financial Instruments. Certain of our notes payable included an embedded conversion option which was required to be recorded at fair value. The estimated fair value of the embedded conversion option was calculated using a probability-weighted Monte Carlo simulation. This valuation method includes Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. Unrealized gains and losses on the fair value of the embedded conversion option are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations.
- Fair Value of Warrants. We estimate the fair value of warrants using the Black-Scholes model, which is affected by our stock price and warrant exercise price, as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility and risk-free interest rate.
- Valuation of Accrued Loss Contingency. Navidea's management believes it is probable that the Company will be required to pay the \$2.9 million modified judgment requested in January 2018, and as such we accrued a loss contingency for that amount as a current liability on the December 31, 2017 consolidated balance sheet. The loss contingency of \$2.9 million was recorded as an additional loss on extinguishment of the CRG Term Loan on the consolidated statement of operations for the year ended December 31, 2017.

## **Contractual Obligations and Commercial Commitments**

The following table presents our contractual obligations and commercial commitments as of December 31, 2017.

		Payments Due By Period									
Contractual Cash Obligations	Total	2018	2019	2020	2021	2022	Thereafter				
Operating lease obligation	\$1,527,784	\$ 328,117	\$ 326,533	\$ 315,594	\$ 304,201	\$ 253,339	\$ —				
Principal and interest on short-term debt	323,002	323,002	_	_	_	_	_				
Principal and interest on long-term debt	2,035,428	2,035,428									
Total contractual cash obligations	\$3,886,214	\$2,686,547	\$ 326,533	\$ 315,594	\$ 304,201	\$ 253,339	\$ —				

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

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

*Interest Rate Risk.* As of December 31, 2017, our \$2.8 million in cash was primarily invested in interest-bearing money market accounts. Due to the low interest rates being realized on these accounts, we believe that a hypothetical 10% increase or decrease in market interest rates would not have a material impact on our consolidated financial position, results of operations or cash flows.

We also have exposure to changes in interest rates on our variable-rate debt obligations. As of December 31, 2017, the interest rate on certain of our debt obligations was the greater of: (a) the U.S. prime rate as reported in The Wall Street Journal plus 6.75%, and (b) 10.0%; both of the above rates reduced by 600 basis points (effective interest rate as of December 31, 2017 was 8.125%). Based on the amount of our variable-rate borrowings at December 31, 2017, which totaled approximately \$2.0 million, an immediate one percentage point increase (decrease) in the U.S. prime rate would increase (decrease) our annual interest expense by approximately \$20,000. This estimate assumes that the amount of variable rate borrowings remains constant for an annual period and that the interest rate change occurs at the beginning of the period.

Foreign Currency Exchange Rate Risk. We do not currently have material foreign currency exposure related to our assets as the majority are denominated in U.S. currency and our foreign-currency based transaction exchange risk is not material. For the years ended December 31, 2017, 2016 and 2015, we recorded foreign currency transaction (losses) gains of approximately \$(27,000), \$(12,000) and \$41,000, respectively.

Equity Price Risk. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. The fair value of our warrant liabilities is determined using various inputs and assumptions, several of which are based on a survey of peer group companies since the warrants are exercisable for common stock of a non-public subsidiary company. As of December 31, 2017, we had approximately \$63,000 of derivative liabilities recorded on our balance sheet related to outstanding MT warrants. Due to the relatively low valuation of the MT warrants, a hypothetical 50% change in our stock price would not have a material effect on the consolidated financial statements.

#### Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, and the related notes, together with the report of Marcum LLP dated March 15, 2018 and the report of BDO USA, LLP dated March 23, 2016, are set forth at pages F-1 through F-41 attached hereto and incorporated herein by reference.

# Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

#### Item 9A. Controls and Procedures

#### **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized, and reported within the specified time periods. As a part of these controls, our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief 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, 2017, 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 our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, understands that our disclosure controls and procedures do not guarantee that all errors and all improper conduct will be prevented. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, a design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments and decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons, or by management override of the control. Further, the design of any system of controls is also based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations of a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

# Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to management and the Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP and that receipts and expenditures of the company are being made only in accordance with authorization of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including the CEO and Interim COO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017 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, 2017, our internal control over financial reporting was effective based on those criteria. Marcum LLP, our independent registered public accounting firm, has issued an attestation report covering our internal control over financial reporting, which begins on page 50.

## **Changes in Internal Control Over Financial Reporting**

Following identification of material weaknesses as of December 31, 2016, we have worked diligently to improve communication between management and the Board of Directors, including committees. We have taken steps to (i) ensure adequate communication between management, the Board of Directors, and its committees, and (ii) educate the Board of Directors, including its committees, about their role in maintaining effective oversight of the Company's financial reporting processes. As a result, our management considers the material weaknesses to be corrected.

Except for the change noted above, during the year ended December 31, 2017, there were no other changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

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

#### **Opinion on Internal Control over Financial Reporting**

We have audited Navidea Biopharmaceuticals, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material aspects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit), and cash flows for the years then ended of the Company, and our report dated March 15, 2018 expressed an unqualified opinion on those financial statements.

# **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion

## **Definition and Limitations of Internal Control over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

/s/ Marcum LLP

New Haven, CT March 15, 2018

# Item 9B. Other Information

None.

# PART III

## Item 10. Directors, Executive Officers and Corporate Governance

#### Directors

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

Name	Age	Committee(s)
Claudine Bruck, Ph.D. (a)	62	_
Anthony S. Fiorino, M.D., Ph.D. (b)	50	_
Michael M. Goldberg, M.D.	59	_
Mark I. Greene, M.D., Ph.D., FRCP	69	Audit; Compensation, Nominating and Governance
Y. Michael Rice	53	Audit (Chairman); Compensation, Nominating and Governance
Eric K. Rowinsky, M.D.	61	Audit; Compensation, Nominating and Governance (Chairman)

- (a) Dr. Bruck was appointed to the Board of Directors effective March 5, 2018.
- (b) Dr. Fiorino resigned from the Board of Directors effective October 9, 2017.

#### **Director Qualifications**

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

- General Management. Directors who have served in senior leadership positions are important to us as they bring experience and perspective in analyzing, shaping, and overseeing the execution of important operational and policy issues at a senior level. These directors' insights and guidance, and their ability to assess and respond to situations encountered in serving on our Board of Directors, are enhanced by their leadership experience developed at businesses or organizations that operated on a global scale, faced significant competition, or involved other evolving business models.
- Industry Knowledge. Because we are a pharmaceutical development company, education or experience in our industry, including medicine, pharmaceutical development, marketing, distribution, or the regulatory environment, is important because such experience assists our Directors in understanding and advising our Company.
- Business Development/Strategic Planning. Directors who have a background in strategic planning, business development, strategic alliances, mergers and acquisitions, and teamwork and process improvement provide insight into developing and implementing strategies for growing our business.
- Finance/Accounting/Control. Knowledge of capital markets, capital structure, financial control, audit, reporting, financial planning, and forecasting are important qualities of our directors because such qualities assist in understanding, advising, and overseeing our Company's capital structure, financing and investing activities, financial reporting, and internal control of such activities.
- Board Experience/Governance. Directors who have served on other public company boards can offer advice and insights with
  regard to the dynamics and operation of a board of directors, the relations of a board to the chief executive officer and other
  management personnel, the importance of particular agenda and oversight matters, and oversight of a changing mix of
  strategic, operational, and compliance-related matters.

## **Biographical Information**

Set forth below is current biographical information about our directors, including the qualifications, experience and skills that make them suitable for service as a director. Each listed director's respective experience and qualifications described below led the Compensation, Nominating and Governance ("CNG") Committee of our Board of Directors to conclude that such director is qualified to serve as a member of our Board of Directors.

#### Director whose term continues until the 2018 Annual Meeting:

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

## Directors whose terms continue until the 2019 Annual Meeting:

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

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

## Directors whose terms continue until the 2020 Annual Meeting:

Michael M. Goldberg, M.D. has served as a director of Navidea since November 2013 and as President and Chief Executive Officer of Navidea since September 2016. Dr. Goldberg has been a Managing Partner of Montaur Capital Partners since January 2007. From 2007 to 2013 Dr. Goldberg managed a life science investment portfolio for Platinum Partners called Platinum-Montaur Life Sciences, LLC. Prior to that, Dr. Goldberg served as the Chief Executive Officer of Emisphere Technologies, Inc., from August 1990 to January 2007 and as its President from August 1990 to October 1995. He also served on Emisphere's board of directors from November 1991 to January 2007. Previous to that, Dr. Goldberg served as Vice President of The First Boston Corp., where he was a founding member of the Healthcare Banking Group. Dr. Goldberg has been a Director of Echo Therapeutics, Inc., AngioLight, Inc., Urigen Pharmaceuticals, Inc., Alliqua BioMedical, Inc., and ADVENTRX Pharmaceuticals, Inc. Dr. Goldberg received a B.S. degree from Rensselaer Polytechnic Institute, an M.D. from Albany Medical College of Union University in 1982, and an M.B.A. from Columbia University Graduate School of Business in 1985.

Mark I. Greene M.D., Ph.D., FRCP has served as a director of Navidea since March 2016. Dr. Greene has been Director of the Division of Immunology, Department of Pathology at University of Pennsylvania School of Medicine since 1986. Dr. Greene was the Associate Director of the Division for Fundamental Research, University of Pennsylvania Cancer Center from 1987-2009 and has been the John Eckman Professor of Medical Science of the University of Pennsylvania School of Medicine since 1989. From 1980 to 1986 he served as an Associate Professor of both Harvard University and Harvard Medical School. His groundbreaking work in erbB receptor function led to the development of Herceptin (Genentech) and to the development of a proprietary method for the rapid, reliable design of allosteric inhibitors of receptors and enzymes. Dr. Greene previously served as a scientific advisor to Navidea's subsidiary, Macrophage Therapeutics, Inc., Ception Therapeutics, Antisome PLC and Fulcrum Technologies and also served as a Member of the Scientific Advisory Boards of Fulcrum Pharmaceuticals, Inc. and Tolerx, Inc. He previously served as an Emeritus Director of Emisphere Technologies, Inc. where he also served as a Director. Additionally, Dr. Greene previously served as a Director of Ribi Immunochem Research, Inc. and currently serves as a Consultant to Martell Biosystems, Inc. Dr. Greene also serves as an advisor to Belgene, SternGreene and Abzed, all start-up companies. Dr. Greene has an outstanding record of contributions to cancer biology and drug discovery that is well-documented in over 400 publications. Dr. Greene is a recipient of many awards and patents and has collaborated with a number of pharmaceutical companies. He received his M.D. (1972) and Ph.D. (1977) from the University of Manitoba, Canada, became a Fellow of the Royal College in 1976 and then joined the faculty of Harvard Medical School in 1976.

#### Director whose term ended effective October 9, 2017:

Anthony S. Fiorino, M.D., Ph.D. served as a Director of Navidea from March 2016 to October 2017. Dr. Fiorino has served as Chief Medical Officer and Chief Operating Officer of Immune Pharmaceuticals, Inc. since August 2017. From December 2015 to July 2017, he served as President and Chief Executive Officer of Triumvira Immunologics, located in Hamilton, Ontario, Canada and Hackensack, New Jersey. Prior to this he was Chief Executive Officer at BrainStorm Cell Therapeutics from June 2014 to November 2015. From January 2013 to May 2014, he was a Managing Director at Greywall Asset Management, a healthcare equity fund, and President and Managing Member of Alchimia Partners, his consulting firm, from February 2008 to December 2012. Dr. Fiorino was also Founder, President and CEO of EnzymeRx, where he led the acquisition of a late-stage pre-clinical biologic and the development of the compound through Phase 1/2 clinical trials and its subsequent sale to 3SBio. Before founding EnzymeRx, Dr. Fiorino worked as a biotechnology and pharmaceuticals analyst and portfolio manager at firms including JP Morgan, Citigroup, and Pequot Capital. Dr. Fiorino earned an M.D. (1996) and a Ph.D. (1995) from the Albert Einstein College of Medicine where he studied the differentiation of liver progenitor cells, a B.S. in Biology from the Massachusetts Institute of Technology (1989) and has authored over 20 publications in the medical and scientific literature.

## **Executive Officers**

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

Name	Age	Position
Frederick O. Cope, Ph.D., F.A.C.N.,		
C.N.S.	71	Senior Vice President and Chief Scientific Officer
Jed A. Latkin	43	Chief Operating Officer, Chief Financial Officer, Treasurer and Secretary

Frederick O. Cope, Ph.D., F.A.C.N., C.N.S., has served as Senior Vice President and Chief Scientific Officer of Navidea since May 2013. Previous to that, Dr. Cope served as Senior Vice President, Pharmaceutical Research and Clinical Development of Navidea from July 2010 to May 2013 and as Vice President, Pharmaceutical Research and Clinical Development from February 2009 to July 2010. Prior to accepting his position with Navidea, Dr. Cope served as the Assistant Director for Research and Head of Program Research Development for The Ohio State University Comprehensive Cancer Center, The James Cancer Hospital and The Richard J. Solove Research Institute. Dr. Cope also served as head of the Cancer and AIDS product development and commercialization program for the ROSS/Abbott Laboratories division, and head of human and veterinary vaccine production and improvement group for Wyeth Laboratories. Dr. Cope served a fellowship in oncology at the McArdle Laboratory for Cancer Research at the University of Wisconsin-Madison and was the honored scientist in residence at the National Cancer Center Research Institute in Tokyo; he is the recipient of the Ernst W. Volwiler Award and nominee for the EANM Marie Curie award. Dr. Cope is also active in a number of professional and scientific organizations such as serving as an editorial reviewer for several professional journals, and as an advisor/director to the research program of Roswell Park Memorial Cancer Center. Dr. Cope received his B.Sc. from the Delaware Valley College of Science and Agriculture, his M.S. from Millersville University of Pennsylvania and his Ph.D. from the University of Connecticut.

Jed A. Latkin has served as 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 currently serves on the boards of directors of the Renewable Fuels Association and Buffalo Lake Advanced Biofuels. Mr. Latkin earned a B.A. from Rutgers University and a M.B.A. from Columbia Business School.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers and directors, and greater than 10% stockholders, to file reports of ownership and changes in ownership of our securities with the Securities and Exchange Commission. Copies of the reports are required by SEC regulation to be furnished to us. Based on our review of these reports and written representations from reporting persons, we believe that all reporting persons complied with all filing requirements during the fiscal year ended December 31, 2017, except for: (1) Frederick O. Cope, Ph.D., Thomas J. Klima, and William J. Regan, who each had one late Form 4 filing related to stock issued in lieu of a portion of their annual cash bonuses; and (2) Y. Michael Rice, who had one late Form 4 filing related to stock donated to a charitable organization.

#### 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 nine meetings in the fiscal year ended December 31, 2017, and each of the directors attended at least 75 percent of the aggregate number of meetings of the Board of Directors and committees (if any) on which he served. It is our policy that all directors attend the Annual Meeting of Stockholders. However, conflicts and unforeseen events may prevent the attendance of a director, or directors. All then-current members of our Board of Directors attended the 2017 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: Y. Michael Rice (Chairman), Mark I. Greene, M.D., Ph.D., FRCP, and Eric K. Rowinsky, M.D., each of whom is "independent" under Section 803A of the NYSE American Company Guide. Prior to October 9, 2017 (the date of Dr. Fiorino's resignation), the members of our Audit Committee were: Mr. Rice (Chairman), Dr. Fiorino, and Dr. Rowinsky. The Board of Directors has determined that Y. Michael Rice meets the requirements of an "audit committee financial expert" as set forth in Section 407(d)(5) of Regulation S-K promulgated by the SEC. The Audit Committee held four meetings in the fiscal year ended December 31, 2017. The Board of Directors adopted a written Amended and Restated Audit Committee Charter on April 30, 2004. A copy of the Amended and Restated Audit Committee Charter is posted on the Company's website at www.navidea.com.

## Compensation, Nominating and Governance Committee

The CNG Committee of the Board of Directors discharges the Board's responsibilities relating to the compensation of the Company's directors, executive officers and associates, identifies and recommends to the Board of Directors nominees for election to the Board, and assists the Board in the implementation of sound corporate governance principles and practices. With respect to its compensation functions, the CNG Committee evaluates and approves executive officer compensation and reviews and makes recommendations to the Board with respect to director compensation, including incentive or equity-based compensation plans; reviews and evaluates any discussion and analysis of executive officer and director compensation included in the Company's annual report or proxy statement, and prepares and approves any report on executive officer and director compensation for inclusion in the Company's annual report or proxy statement required by applicable rules and regulations; and monitors and evaluates, at the Committee's discretion, matters relating to the compensation and benefits structure of the Company and such other domestic and foreign subsidiaries or affiliates, as it deems appropriate. The members of our CNG Committee are: Eric K. Rowinsky, M.D. (Chairman), Mark I. Greene, M.D., Ph.D., FRCP, and Y. Michael Rice. The CNG Committee held two meetings in the fiscal year ended December 31, 2017 to complement compensation-related discussions held by the full Board. The Board of Directors adopted a written 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 all senior executive compensation, all awards under our cash bonus plan, and awards under our equity-based compensation plans.

Philosophy and Goals of Executive Compensation Plans. The CNG Committee's philosophy for executive compensation is to:

- Pay for performance: The CNG Committee believes that our executives should be compensated based upon their ability to
  achieve specific operational and strategic results. Therefore, our compensation plans are designed to provide rewards for the
  individual's contribution to our performance.
- Pay commensurate with other companies categorized as value creators: The CNG Committee has set a goal that the Company
  should move toward compensation levels for senior executives that are, at a minimum, at the 40th to 50th percentile for similar
  executives in the workforce while taking into account current market conditions and Company performance. This allows us to
  attract, hire, reward and retain senior executives who formulate and execute our strategic plans and drive exceptional results.

To assess whether our programs are competitive, the CNG Committee reviews compensation information of peer companies, national data and trends in executive compensation to help determine the appropriateness of our plans and compensation levels. These reviews, and the CNG Committee's commitment to pay for performance, become the basis for the CNG Committee's decisions on compensation plans and individual executive compensation payments.

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

- Reward executives based upon overall company performance, their individual contributions and creation of stockholder value;
- Encourage executives to make a long-term commitment to our Company; and
- Align executive incentive plans with the long-term interests of stockholders.

The CNG Committee reviews competitive information and individual compensation levels at least annually. During the review process, the CNG Committee addresses the following questions:

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

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

The CNG Committee does not believe that our compensation policies and practices for our employees give rise to risks that are reasonably likely to have a material adverse effect on the Company. As noted below, our incentive-based compensation is generally tied to Company financial performance (i.e., revenue, gross margin or budgeted expense targets) or product development goals (i.e., clinical trial progress or regulatory milestones). The CNG Committee believes that the existence of these financial performance incentives creates a strong motivation for Company employees to contribute towards the achievement of strong, sustainable financial and development performance, and believes that the Company has a strong set of internal controls that minimize the risk that financial performance can be misstated in order to achieve incentive compensation payouts.

In addition to the aforementioned considerations, the CNG Committee also takes into account the outcome of stockholder advisory ("sayon-pay") votes, taken every three years, on the compensation of our Chief Executive Officer, Chief Financial Officer, and our next three highest-paid executive officers (the "Named Executive Officers"). At the Annual Meeting of Stockholders held on June 29, 2017, approximately 75% of our stockholders voted in favor of the resolution relating to the compensation of our Named Executive Officers. The CNG Committee believes this affirmed stockholders' support of the Company's executive compensation program. The CNG Committee will continue to consider the results of future say-on-pay votes when making future compensation decisions for the executive officers.

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

Scope of Authority of the CNG Committee. The Board of Directors has authorized the CNG Committee to establish the compensation programs for all executive officers and to provide oversight for compliance with our compensation philosophy. The CNG Committee delegates the day-to-day administration of the compensation plans to management (except with respect to our executive officers), but retains responsibility for ensuring that the plan administration is consistent with the Company's policies. Annually, the CNG Committee sets the compensation for our executive officers, including objectives and awards under incentive plans. The Chief Executive Officer provides input for the CNG Committee regarding the performance and appropriate compensation of the other officers. The CNG Committee gives considerable weight to the Chief Executive Officer's evaluation of the other officers because of his direct knowledge of each officer's performance and contributions. The CNG Committee also makes recommendations to the Board of Directors on appropriate compensation for the non-employee directors. In addition to overseeing the compensation of executive officers, the CNG Committee approves awards under short-term cash incentive and long-term equity-based compensation plans for all other employees. For more information on the CNG Committee's role, see the CNG Committee's charter, which can be found on our website at www.navidea.com.

Independent Compensation Expertise. The CNG Committee is authorized to 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 Pearl Meyer & Partners ("Pearl Meyer") as its independent consultant to assist in the determination of the reasonableness and competitiveness of the executive compensation plans and senior executives' individual compensation levels for fiscal 2015. No conflict of interest exists that would prevent Pearl Meyer from serving as independent consultant to the CNG Committee.

For fiscal 2015, Pearl Meyer performed a benchmark compensation review of our key executive positions, including our Named Executive Officers. Pearl Meyer utilized both published survey and proxy reported data from compensation peers, with market data aged to March 1, 2016 by an annualized rate of 3.0%, the expected pay increase in 2016 for executives in the life sciences industry.

In evaluating appropriate executive compensation, it is common practice to set targets at a point within the competitive marketplace. The CNG Committee sets its competitive compensation levels based upon its compensation philosophy. Following completion of the Pearl Meyer study for 2015, the CNG Committee noted that our overall executive compensation was, in aggregate, below the 25th percentile for an established peer group of companies.

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

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

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

Pearl Meyer and the CNG Committee used the publicly available compensation information for these companies to analyze our competitive position in the industry. Base salaries and short-term and long term incentive plans of the executives of these companies were reviewed to provide background and perspective in analyzing the compensation levels for our executives.

Specific Elements of Executive Compensation

Base Salary. Using information gathered by Pearl Meyer, peer company data, national surveys, general compensation trend information and recommendations from management, the CNG Committee approved the fiscal 2015 base salaries for our senior executives. Base salaries for senior executives are set using the CNG Committee's philosophy that compensation should be competitive and based upon performance. Executives should expect that their base salaries, coupled with a cash bonus award, would provide them the opportunity to be compensated at or above the competitive market at the 40th to 50th percentile.

Based on competitive reviews of similar positions, industry salary trends, overall company results and individual performance, salary increases may be approved from time to time. The CNG Committee reviews and approves base salaries of all executive officers. In setting specific base salaries for fiscal 2015, the CNG Committee considered published proxy data for similar positions at peer group companies.

The following table shows the changes in base salaries for the Named Executive Officers that were approved for fiscal 2017 compared to the approved salaries for fiscal 2016:

	Fis	Fiscal 2017		scal 2016	
Named Executive Officer	Base	Base Salary <sup>(a)</sup>		se Salary <sup>(a)</sup>	Change <sup>(b)</sup>
Michael M. Goldberg, M.D.	\$	400,000	\$	400,000	0.0%
Frederick O. Cope, Ph.D.		279,130		279,130	0.0%
Thomas J. Klima <sup>(c)</sup>		270,000		270,000	0.0%
Jed A. Latkin <sup>(d)</sup>		325,000		300,000	8.3%
William J. Regan (e)		250,000		250,000	0.0%

- (a) The amount shown for fiscal 2017 and 2016 is the approved annual salary of the Named Executive Officer in effect at the end of each year, or at the date of separation. The actual amount paid to the Named Executive Officer during fiscal 2017 and 2016 is shown under "Salary" in the Summary Compensation table below.
- (b) Due to the Company's financial difficulties in 2017, Named Executive Officers did not receive salary increases in 2017, except for Mr. Latkin.
- (c) Mr. Klima separated from the Company effective March 8, 2017.
- (d) Mr. Latkin received an increase in base salary in connection with his appointment as Chief Operating Officer and Chief Financial Officer of the Company effective May 4, 2017.
- (e) Mr. Regan separated from the Company effective June 30, 2017.

The CNG Committee has not approved any changes to base salaries of Named Executive Officers for fiscal 2018.

Short-Term Incentive Compensation. Our executive officers, along with all of our employees, are eligible to participate in our annual cash bonus program, which has four primary objectives:

- Attract, retain and motivate top-quality executives who can add significant value to the Company;
- Create an incentive compensation opportunity that is an integral part of the employee's total compensation program;
- Reward participants' contributions to the achievement of our business results; and
- Provide an incentive for individuals to achieve corporate objectives that are tied to our strategic goals.

The cash bonus compensation plan provides each participant with an opportunity to receive an annual cash bonus based on our Company's performance during the fiscal year. Cash bonus targets for senior executives are determined as a percentage of base salary, based in part on published proxy data for similar positions at peer group companies. The following are the key provisions of the cash bonus compensation plan:

- The plan is administered by the CNG Committee, which has the power and authority to establish, adjust, pay or decline to pay the cash bonus for each participant, including the power and authority to increase or decrease the cash bonus otherwise payable to a participant. However, the Committee does not have the power to increase, or make adjustments that would have the effect of increasing, the cash bonus otherwise payable to any executive officer. The Committee has the right to delegate to the Chief Executive Officer its authority and responsibilities with respect to the cash bonuses payable to employees other than executive officers.
- All Company employees are eligible to participate, except interns.

- The CNG Committee is responsible for specifying the terms and conditions for earning cash bonuses, including establishing specific performance objectives. Cash bonuses payable to executive officers for 2017 were intended to constitute "qualified performance-based compensation" for purposes of Section 162(m) of the Internal Revenue Code.
- As soon as reasonably practicable after the end of each fiscal year, the CNG Committee determines whether and to what extent
  each specified business performance objective has been achieved and the amount of the cash bonus to be paid to each
  participant.

In June 2017, the Board of Directors established the fiscal 2017 targets and performance measures for all Company employees. For fiscal 2017, 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 2017 were as follows:

- Achievement of various development goals for diagnostic applications of the Company's Manocept platform, including:
  - o Complete enrollment in the Company's NAV3-23 Phase 1 trial, subject to a maximum 5% reduction of bonus if not achieved;
  - o Achieve 50% of target enrollment in the Company's NAV3-21 Phase 1 trial, subject to a maximum 5% reduction of bonus if not achieved:
  - o Develop an approvable plan for activated macrophage-caused inflammation, subject to a maximum 10% reduction of bonus if not achieved;
  - o Commence a clinical study for CV imaging of coronary arteries, subject to a maximum 10% reduction of bonus if not achieved; and
  - o Commence a clinical study for NASH imaging, subject to a maximum 10% reduction of bonus if not achieved.
- Achievement of various development goals for therapeutic applications of the Company's Manocept platform, including:
  - o Develop a prototype oral formulation of Manocept, subject to a maximum 10% reduction of bonus if not achieved;
  - o Develop new carrier prototypes, subject to a maximum 10% reduction of bonus if not achieved; and
  - o File intellectual property claims on new advances, subject to a maximum 10% reduction of bonus if not achieved.
- Achievement of various corporate goals, including:
  - o Structure and initiate drafting of MT spinout or funding transaction, subject to a maximum 10% reduction of bonus if not achieved; and
  - o Reduce debt and expenses so non-discretionary expenses are less than a specified target amount, subject to a maximum 20% reduction of bonus if not achieved.

For the Named Executive Officers, cash bonus targets fiscal 2017 remained unchanged from 2016 and were as follows:

	Target Cash Bonus	Target Cash Bonus
Named Executive Officer	(% of Salary)	(\$ Amount)
Michael M. Goldberg, M.D.	75.0% \$	300,000
Frederick O. Cope, Ph.D.	35.0%	97,696
Thomas J. Klima <sup>(a)</sup>	35.0%	94,500
Jed A. Latkin	75.0%	243,750
William J. Regan <sup>(b)</sup>	35.0%	87,500

- (a) Mr. Klima separated from the Company effective March 8, 2017 and therefore will not be paid a bonus for fiscal 2017.
- (b) Mr. Regan separated from the Company effective June 30, 2017 and therefore will not be paid a bonus for fiscal 2017.

On February 20, 2018, the Board of Directors determined the amounts to be awarded as 2017 bonuses to all employees, including the Named Executive Officers. The Board of Directors recognized the achievement of all 2017 bonus goals and thus awarded bonuses at 100% of target amounts for all employees, to be paid 50% in stock immediately and 50% in cash at such time as the Company's financial position allows a cash payment. However, Dr. Goldberg's and Mr. Latkin's bonus awards will be 100% cash, to be paid following achievement of certain additional goals set by the Board and at such time as the Company's financial position allows a cash payment.

Also on February 20, 2018, the Board of Directors determined the 2018 cash bonus targets for Named Executive Officers as follows:

	Target Cash Bonus	Target Cash Bonus		
Named Executive Officer	(% of Salary)	(\$ Amount)		
Michael M. Goldberg, M.D.	75.0% \$	300,000		
Frederick O. Cope, Ph.D.	35.0%	97,696		
Jed A. Latkin	75.0%	243,750		

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. Equity awards for senior executives are determined as a percentage of base salary, based on published proxy data for similar positions at peer group companies. Stock option awards have vesting schedules over several years to promote long-term performance and retention of the recipient, and restricted stock awards may include specific performance criteria for vesting or vest over a specified period of time. In April 2017, the CNG Committee vested 50,000 shares of restricted stock held by Dr. Cope after determining that the vesting events would never occur due to changes in the Company's development programs.

In May 2017, the Company awarded options to purchase 1,000,000 shares of common stock to Mr. Latkin in connection with his appointment as permanent Chief Operating Officer and Chief Financial Officer. The options were awarded with the following terms: (1) 333,334 options with an exercise price of \$0.65 will be exercisable on or after May 4, 2017, so long as the closing price of the underlying common stock equals or exceeds \$0.85 per share; (2) 333,333 options with an exercise price of \$0.75 will be exercisable on or after December 31, 2017, so long as the closing price of the underlying common stock equals or exceeds \$1.00 per share; and (3) 333,333 options with an exercise price of \$1.00 will be exercisable on or after December 31, 2018, so long as the closing price of the underlying common stock equals or exceeds \$1.25 per share. The options will expire on the tenth anniversary of the date of grant. The CNG Committee believes that, given the increased responsibilities of the Chief Operating Officer and Chief Financial Officer related to the Company's legal and financial difficulties at the time of his appointment, Mr. Latkin's compensation, including his equity awards, is commensurate with that of his predecessor. We did not grant equity awards to our Named Executive Officers in 2017, other than Mr. Latkin.

Other Benefits and Perquisites. The Named Executive Officers are generally eligible to participate in other benefit plans on the same terms as other employees. These plans include medical, dental, vision, disability and life insurance benefits, and our 401(k) retirement savings plan (the "401(k) Plan").

Our vacation policy allows employees to carry up to 40 hours of unused vacation time forward to the next fiscal year. Any unused vacation time in excess of the amount eligible for rollover is generally forfeited.

Our Named Executive Officers are considered "key employees" for purposes of Internal Revenue Code ("IRC") Section 125 Plan non-discrimination testing. Based on such non-discrimination testing, we determined that our Section 125 Plan was "top-heavy" for fiscal 2017. As such, 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." As such, 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 \$630,000.

We also pay group long-term disability insurance premiums on behalf of all employees, including the Named Executive Officers. The benefit provides long-term disability insurance coverage at 60% of the employee's annual salary, up to a maximum of \$10,000 per month, beginning 180 days after the date of disability and continuing through age 65.

401(k) Retirement Plan. All employees are given an opportunity to participate in our 401(k) Plan, following a new-hire waiting period. The 401(k) Plan allows participants to have pre-tax amounts withheld from their pay and provides for a discretionary employer matching contribution (currently, a 40% match up to 5% of salary in the form of our common stock). Participants may invest their contributions in various fund options, but are prohibited from investing their contributions in our common stock. Participants are immediately vested in both their contributions and Company matching contributions. The 401(k) Plan qualifies under section 401 of the Internal Revenue Code, which provides that employee and company contributions and income earned on contributions are not taxable to the employee until withdrawn from the Plan, and that we may deduct our contributions when made.

#### **Employment Agreements**

Our senior executive officers are generally employed under employment agreements which specify the terms of their employment such as base salary, benefits, paid time off, and post-employment benefits as shown in the tables below. Our employment agreements also specify that if a change in control occurs with respect to our Company and the employment of a senior executive officer is concurrently or subsequently terminated:

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

then, the senior executive officer would be paid a severance payment as disclosed in the tables below. For purposes of such employment agreements, a change in control includes:

- the acquisition, directly or indirectly, by a person (other than our Company, an employee benefit plan established by the Board of Directors, or a participant in a transaction approved by the Board of Directors for the principal purpose of raising additional capital) of beneficial ownership of 30% or more of our securities with voting power in the next meeting of holders of voting securities to elect the Directors;
- a majority of the Directors elected at any meeting of the holders of our voting securities are persons who were not nominated by our then current Board of Directors or an authorized committee thereof;
- our stockholders approve a merger or consolidation of our Company with another person, other than a merger or consolidation in which the holders of our voting securities outstanding immediately before such merger or consolidation continue to hold voting securities in the surviving or resulting corporation (in the same relative proportions to each other as existed before such event) comprising 80% or more of the voting power for all purposes of the surviving or resulting corporation; or
- our stockholders approve a transfer of substantially all of our assets to another person other than a transfer to a transferee, 80% or more of the voting power of which is owned or controlled by us or by the holders of our voting securities outstanding immediately before such transfer in the same relative proportions to each other as existed before such event.

Michael M. Goldberg, M.D. Dr. Goldberg was employed under a 12-month employment agreement effective through September 22, 2017. The employment agreement provided for an annual base salary of \$400,000. For the calendar year ending December 31, 2017, the CNG Committee determined that the maximum bonus payment to Dr. Goldberg would be \$300,000.

Dr. Goldberg's employment agreement also provided 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 Dr. Goldberg.
- Resignation All salary, benefits and other payments shall cease at the time of resignation, and the Company shall have no further obligations to Dr. Goldberg, except that the Company shall pay the value of any accrued but unused paid time off, 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 Dr. Goldberg's estate under any plan, program, policy, practice, contract, or arrangement in which Dr. Goldberg 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 Dr. Goldberg's estate the value of any accrued but unused paid time off 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 Dr. Goldberg under any plan, program, policy, practice, contract, or arrangement in which Dr. Goldberg 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 Dr. Goldberg's regular salary not replaced by disability insurance coverage for six months following the date of disability. The Company shall also pay to Dr. Goldberg the value of any accrued but unused paid time off and the amount of any accrued but previously unpaid salary through the date of such termination.
- Without Cause or by Dr. Goldberg for Good Reason The Company shall pay the value of any accrued but unused paid time off, 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: (1) 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"); (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 (3) without duplication to (2), the unpaid bonus, if any, for the year in which the termination occurs, prorated to the date of termination. The Company will also pay such other benefits required to be paid or provided to Dr. Goldberg under any plan, program, policy, practice, contract, or arrangement in which Dr. Goldberg 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 paid time off, 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: (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 (3) without duplication to (2), the unpaid bonus, if any, for the year in which the termination occurs, prorated to 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.

Although Dr. Goldberg's employment agreement expired on September 22, 2017, the terms of the agreement provide for continuation of certain terms of the employment agreement as long as Dr. Goldberg continues to be an employee of the Company following expiration of the agreement.

In connection with Dr. Goldberg's appointment as Chief Executive Officer of the Company, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of a new Stock Incentive Plan. If approved, these stock options will vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant. If a new Stock Incentive Plan is not approved, the Company will be obligated to pay in cash the implied market value of the options at the time of "exercise" by Dr. Goldberg, assuming the share price exceeds \$2.50 and all other vesting conditions are met.

Frederick O. Cope, Ph.D. Dr. Cope was employed under a 24-month employment agreement effective through December 31, 2014. The employment agreement provided for an annual base salary of \$271,000. Effective May 1, 2013, Dr. Cope's annual base salary was increased to \$279,130. For the calendar year ending December 31, 2017, the CNG Committee determined that the maximum bonus payment to Dr. Cope would be \$97,696. Although Dr. Cope's employment agreement expired on December 31, 2014, the terms of the agreement provide for continuation of certain terms of the employment agreement as long as Dr. Cope continues to be an employee of the Company following expiration of the agreement.

Dr. Cope's employment agreement also provided 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 Dr. Cope.
- Resignation All salary, benefits and other payments shall cease at the time of resignation, and the Company shall have no further obligations to Dr. Cope, except that the Company shall pay the value of any accrued but unused paid time off, 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 health, dental and similar insurance or benefits as were provided to Dr. Cope immediately before his death for the longer of 12 months or the full unexpired term of the employment agreement. The Company shall also pay to Dr. Cope's estate the value of any accrued but unused paid time off 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 health, dental and similar insurance or benefits as were provided to Dr. Cope immediately before termination for the longer of 12 months or the full unexpired term of the employment agreement. In addition, the Company will pay the balance of Dr. Cope's regular salary not replaced by disability insurance coverage for six months following the date of disability. The Company shall also pay to Dr. Cope the value of any accrued but unused paid time off and the amount of any accrued but previously unpaid salary through the date of such termination.
- Without Cause The Company shall pay the value of any accrued but unused paid time off, 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 \$245,000. The Company will also pay health, dental and similar insurance or benefits as were provided to Dr. Cope immediately before termination for the longer of 12 months or the full unexpired term of the employment agreement.
- End of Term The Company shall pay the value of any accrued but unused paid time off, 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 \$245,000.
- Change in Control The Company shall pay the value of any accrued but unused paid time off, 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 \$367,500. The Company will also pay health, dental and similar insurance or benefits as were provided to Dr. Cope immediately before termination for the longer of 12 months or the full unexpired term of the employment agreement.

*Jed A. Latkin*. Mr. Latkin is employed under an annually renewing employment agreement. The employment agreement provides for an annual base salary of \$325,000. For the calendar year ending December 31, 2017, the CNG Committee determined that the maximum bonus payment to Mr. Latkin would be \$243,750.

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 paid time off, 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 paid time off 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 paid time off 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 paid time off, 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"). In addition, certain share options shall vest immediately and shall be exercisable for six months following the termination. 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 paid time off, 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

Eric K. Rowinsky, M.D. (Chairman) Mark I. Greene, M.D., Ph.D., FRCP Y. Michael Rice

## Compensation, Nominating and Governance Committee Interlocks and Insider Participation

The current members of our CNG Committee are: Eric K. Rowinsky, M.D. (Chairman), Mark I. Greene, M.D., Ph.D., FRCP, and Y. Michael Rice. None of these individuals were at any time during the fiscal year ended December 31, 2017, or at any other time, an officer or employee of the Company.

No director who served on the CNG Committee during 2017 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 2017.

#### 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 2017**

Named Executive Officer	Year	Salary	 (a) Stock Awards	 (b) Option Awards	In	(c) Non-Equity centive Plan compensation	(d) All Other ompensation	Co	Total ompensation
Michael M. Goldberg (e) President and Chief Executive Officer	2017 2016 2015	\$ 427,222 83,077 —	\$ _ _ _	\$ =	\$	410,768 — —	\$ 8,067 436 —	\$	846,057 83,513
Frederick O. Cope, Ph.D. Senior Vice President and Chief Scientific Officer	2017 2016 2015	\$ 279,130 279,130 279,130	\$ _ _ _	\$  	\$	97,969 54,710 54,709	\$ 6,906 6,735 6,657	\$	383,732 340,575 495,522
Thomas J. Klima <sup>(f)</sup> Senior Vice President and Chief Commercial Officer	<ul><li>2017</li><li>2016</li><li>2015</li></ul>	\$ 66,635 270,000 270,000	\$ — — 192,900	\$ — — 112,163	\$	52,920 52,921	\$ 2,326 3,114	\$	66,635 325,246 631,098
Jed A. Latkin <sup>(g)</sup> Chief Operating Officer and Chief Financial Officer	2017 2016 2015	\$ 316,458 163,309 —	\$ _ _ _	\$ 125,833 39,992 —	\$	366,653	\$ 5,429 	\$	814,373 203,301 —
William J. Regan <sup>(h)</sup> Senior Vice President and Chief Compliance Officer	<ul><li>2017</li><li>2016</li><li>2015</li></ul>	\$ 129,808 250,000 250,000	\$ _ _ _	\$ 	\$	49,000 49,001	\$ 3,327 6,142 6,410	\$	133,135 305,142 463,307

- (a) Amount represents the aggregate grant date fair value of restricted shares in accordance with FASB ASC Topic 718. Assumptions made in the valuation of stock awards are disclosed in Note 1(e) of the Notes to the Consolidated Financial Statements in this Form 10-K.
- (b) Amount represents the aggregate grant date fair value 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
- (c) Amount represents the total non-equity incentive plan amounts which have been approved by the Board of Directors as of the date this filing, and are disclosed for the year in which they were earned (i.e., the year to which the service relates).
  - On April 25, 2017, the Board of Directors awarded a cash bonus to each of Dr. Goldberg and Mr. Latkin in recognition of the successful closing of the Company's sale of certain assets to Cardinal Health 414, LLC, which occurred on March 3, 2017.
  - For fiscal 2017, the Board of Directors determined that fifty percent of the 2017 bonus amount payable would be paid in stock in lieu of cash for all employees except Dr. Goldberg and Mr. Latkin, who will receive one hundred percent of their bonuses in cash, to be paid following achievement of certain additional goals set by the Board. As such, Dr. Cope was awarded 135,694 shares of common stock of the Company valued at \$0.36 per share, the closing price of Navidea's common stock on February 20, 2018. Since these shares represent incentive compensation earned in 2017, they are reported in this column, and not included in the column "Stock Awards." Payment of the cash portion of the 2017 bonus awards has been deferred until such time as the Company's financial position allows a cash payment.
  - For fiscal 2016, the Board of Directors determined that a portion of the 2016 bonus amount payable would be paid in stock in lieu of cash. The portion of the 2016 bonus amount payable in cash is either fifty percent or thirty-three percent, as determined by the Board of Directors. As such, Dr. Cope, Mr. Klima and Mr. Regan were awarded 70,492, 50,885 and 63,135, respectively, shares of common stock of the Company valued at \$0.52 per share, the closing price of Navidea's common stock on February 6, 2017. Since these shares represent incentive compensation earned in 2016, they are reported in this column, and not included in the column "Stock Awards." The cash portion of the 2016 bonus awards was paid on March 15, 2017. The Board of Directors did not award bonuses to Dr. Goldberg and Mr. Latkin for 2016.
  - For fiscal 2015, the Board of Directors initially determined that fifty percent of the 2015 bonus amount payable to certain executive officers would be paid in stock options in lieu of cash, calculated based on the Black-Scholes value of the options on the date of grant. As such, Dr. Cope, Mr. Klima, Mr. Larson and Mr. Regan were awarded, respectively, options to purchase 58,510, 56,598, 54,501 and 52,405 shares of common stock of the Company at an exercise price of \$0.98 per share, vesting immediately upon the date of grant and expiring after ten years. Since these options represent incentive compensation earned in 2015, they are reported in this column, and not included in the column "Option Awards." In February 2017, the Board of Directors determined that the amounts previously awarded as 2015 bonuses would be subject to the same split

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

- (d) Amount represents additional compensation as disclosed in the All Other Compensation table below.
- (e) Dr. Goldberg commenced employment with the Company effective September 22, 2016. In connection with Dr. Goldberg's appointment as Chief Executive Officer of the Company, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of a new Stock Incentive Plan. If approved, these stock options will vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant. If the plan is not approved, the Company will be obligated to pay the implied market value in cash.
- (f) Mr. Klima separated from the Company effective March 8, 2017.
- (g) Mr. Latkin commenced employment with the Company effective April 21, 2016.
- (h) Mr. Regan separated from the Company effective June 30, 2017.

# All Other Compensation

The following table describes each component of the amounts shown in the "All Other Compensation" column in the Summary Compensation table above.

# All Other Compensation Table for Fiscal 2017

Named Executive Officer	Year	(a) deimbursement of Additional Tax Liability Related to Insurance Premiums	(b) 401(k) Plan Employer Matching Contribution	(c) Opt-Out Bonus	Total All Othe Compensa	
Michael M. Goldberg, M.D.	2017 2016 2015	\$ 2,667 436 —	\$ 5,400	\$	\$	8,067 436 —
Frederick O. Cope, Ph.D.	2017 2016 2015	\$ 1,506 1,435 1,357	\$ 5,400 5,300 5,300	\$ <u> </u>	\$	6,906 6,735 6,657
Thomas J. Klima	2017 2016 2015	\$ 2,316 1,310	\$ 1,804	\$ <u> </u>	\$	2,326 3,114
Jed A. Latkin	2017 2016 2015	\$ 29 	\$ 5,400 — —	\$	\$	5,429
William J. Regan	2017 2016 2015	\$ 54 106 110	\$ 3,273 5,036 5,300	\$ — 1,000 1,000	\$	3,327 6,142 6,410

<sup>(</sup>a) Amount represents reimbursement of the lost tax benefit due to the ineligibility of our Named Executive Officers to pay their portion of medical, dental, and vision premiums on a pre-tax basis under our IRC Section 125 Plan.

<sup>(</sup>b) Amount represents the value of the common stock accrued for contribution to the Named Executive Officer's account in our 401(k) Plan as calculated on a quarterly basis.

<sup>(</sup>c) Amount represents additional bonus paid for non-participation in the Company's medical plan.

### 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 2017, 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 \$846,057;
- The median of the annual total compensation of all of our employees, excluding the Chief Executive Officer, was \$79,921; and
- The ratio of the annual total compensation of our CEO to the median of the annual total compensation of all other employees was 11 to 1

In determining the pay ratio information provided above, we first identified our median employee for 2017 by using the following methodology:

- We selected December 31, 2017 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 tables set forth the expected benefit to be received by each of our Named Executive Officers in the event of his termination resulting from various scenarios, assuming a termination date of December 31, 2017 and a stock price of \$0.36, our closing stock price on December 29, 2017.

Michael M. Goldberg, M.D.

Cash payments:	Fo	r Cause	Re	signation	]	Death	<u>D</u>	isability	Without Cause	End of Term	Change in Control
Severance (a)	\$	_	\$	_	\$	_	\$	_	\$1,166,667	\$1,166,667	\$1,216,667
Disability supplement (b)		_		_		_		197,600		_	_
Paid time off (c)		7,692		7,692		7,692		7,692	7,692	7,692	7,692
2017 401(k) match <sup>(d)</sup>		5,400		5,400		5,400		5,400	5,400	5,400	5,400
Continuation of benefits (e)					_	25,723	_	25,723	30,010		
Total	\$	13,092	\$	13,092	\$	38,816	\$	236,416	\$1,209,769	\$1,179,759	\$1,229,759

- (a) Severance amounts are pursuant to Dr. Goldberg's employment agreement.
- (b) During the first 6 months of disability, the Company will supplement disability insurance payments to Dr. Goldberg to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays \$100 per week for a maximum of 24 weeks.
- (c) Amount represents the value of 40 hours of accrued but unused vacation time as of December 31, 2017.
- (d) Amount represents the value of 12,857 shares of Company stock which was accrued during 2017 as the Company's 401(k) matching contribution but was unissued as of December 31, 2017.
- (e) Amount represents 12 months or 14 months, as applicable, of medical, dental and vision insurance premiums at rates in effect at December 31, 2017.
- (f) This table does not include 5,000,000 options which are subject to stockholder approval of a new Stock Incentive Plan. If the plan is not approved, the Company will be obligated to pay the implied market value in cash.

Frederick O. Cope, Ph.D.

	Fo	r Cause	Res	signation	 Death	Disability	Without Cause	End of Term	Change in Control
Cash payments:									
Severance (a)	\$	_	\$	_	\$ _	\$ —	\$ 245,000	\$ 245,000	\$ 367,500
Disability supplement (b)		_		_	_	137,165	_		_
Paid time off (c)		5,368		5,368	5,368	5,368	5,368	5,368	5,368
2017 401(k) match <sup>(d)</sup>		5,400		5,400	5,400	5,400	5,400	5,400	5,400
Continuation of benefits (e)		_		_	17,607	17,607	17,607	_	17,607
Stock option vesting acceleration (f)		_		_	_	_	_		_
Total	\$	10,768	\$	10,768	\$ 28,375	\$ 165,540	\$ 273,375	\$ 255,768	\$ 395,875

- (a) Severance amounts are pursuant to Dr. Cope's employment agreement.
- (b) During the first 6 months of disability, the Company will supplement disability insurance payments to Dr. Cope to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays \$100 per week for a maximum of 24 weeks.
- (c) Amount represents the value of 40 hours of accrued but unused vacation time as of December 31, 2017.
- (d) Amount represents the value of 9,598 shares of Company stock which was accrued during 2017 as the Company's 401(k) matching contribution but was unissued as of December 31, 2017.
- (e) Amount represents 12 months of medical, dental and vision insurance premiums at rates in effect at December 31, 2017.
- (f) Pursuant to Dr. Cope's stock option agreements, all unvested stock options outstanding will vest upon termination at the end of the term of his employment agreement, termination without cause, or a change in control. Amount represents the value of the stock at \$0.36, the closing price of the Company's stock on December 29, 2017, less the exercise price of the options. Amount does not include stock options with an exercise price higher than \$0.36, the closing price of the Company's stock on December 29, 2017.

	Fo	r Cause	Res	ignation_	]	Death	Disability	_	Without Cause	nd of Term		hange in Control
Cash payments:												
Severance (a)	\$	_	\$	_	\$	_	\$ —	9	\$ 379,167	\$ _	\$	988,542
Disability supplement (b)		_		_		_	160,100		_	_		_
Paid time off (c)		6,250		6,250		6,250	6,250		6,250	6,250		6,250
2016 401(k) match <sup>(d)</sup>		5,400		5,400		5,400	5,400		5,400	5,400		5,400
Continuation of benefits (e)		_		_		500	500		500	_		_
Stock option vesting acceleration (f)										 		
Total	\$	11,650	\$	11,650	\$	12,150	\$ 172,250		\$ 391,316	\$ 11,650	\$1	,000,192

- (a) Severance amounts are pursuant to Mr. Latkin's employment agreement.
- (b) During the first 6 months of disability, the Company will supplement disability insurance payments to Mr. Latkin to achieve 100% salary replacement. The Company's short-term disability insurance policy currently pays \$100 per week for a maximum of 24 weeks.
- (c) Amount represents the value of 40 hours of accrued but unused vacation time as of December 31, 2017.
- (d) Amount represents the value of 9,068 shares of Company stock which was accrued during 2017 as the Company's 401(k) matching contribution but was unissued as of December 31, 2017.
- (e) Amount represents 12 months of dental insurance premiums at rates in effect at December 31, 2017.
- (f) Pursuant to Mr. Latkin's stock option agreements, all unvested stock options outstanding will vest upon termination without cause or a change in control. Amount represents the value of the stock at \$0.36, the closing price of the Company's stock on December 29 2017, less the exercise price of the options. Amount does not include stock options with an exercise price higher than \$0.36, the closing price of the Company's stock on December 29, 2017.

### Tax Consequences

In structuring our executive compensation program, the CNG Committee takes into account the tax treatment of our compensation arrangements. For example, the CNG Committee reviews and considers the deductibility of executive compensation under Section 162(m) of the Internal Revenue Code ("Section 162(m)"). Section 162(m) generally provides that the Company may not deduct compensation paid to a "covered employee" (generally our named executive officers serving on the last day of the year other than the chief financial officer) to the extent it exceeds \$1 million. Qualified performance-based compensation paid pursuant to shareholder approved plans is not subject to the \$1 million deduction limit, provided that certain requirements are satisfied.

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).

The Tax Cuts and Jobs Act, which was enacted on December 22, 2017, includes a number of significant changes to Section 162(m), such as the repeal of the qualified performance-based compensation exemption and the expansion of the definition of "covered employees" (for example, by including the chief financial officer and certain former named executive officers as covered employees).

As a result of these changes, except as otherwise provided in the transition relief provisions of the Tax Cuts and Jobs Act, compensation paid to any of our covered employees generally will not be deductible in 2018 or future years, to the extent that it exceeds \$1 million.

# Grants of Plan-Based Awards

The following table sets forth certain information about plan-based awards that we made to the Named Executive Officers during fiscal 2017. 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 2017

Named Executive Officer	Grant Date	No	Plan Aw	U y In	nder ncentive ds (a)	Payouts Equity I Plan A	ncentive wards	All Other Stock Awards: Number of Shares of Stock	All Other Option Awards: Number of Securities Underlying Options	Pri Op	ercise ce of otion vards	D F Va St a Op	ant ate air due of ock nd tion ards
Michael M. Goldberg,													
M.D.	N/A	\$		\$	300,000	_	_	_	_	\$	_	\$	— (a)
	/.												
Frederick O. Cope, Ph.D.	N/A	\$	_	\$	97,696	_	_	_	_	\$	_	\$	(a)
Thomas I Viima	NI/A	¢.		Φ								Φ	(1-)
Thomas J. Klima	N/A	Þ	_	Э	_	_	_	_	_		_	Э	— (b)
Jed A. Latkin	N/A	¢	_	Ф	243,750				_	Ф		\$	(0)
Jeu A. Laikiii	5/4/2017			\$	243,730				333,334		0.65		— (a) 3,533 (c)
	5/4/2017			\$					333,333				5,567 (d)
	5/4/2017		_	\$	_	_	_	_	333,333				5,733 (e)
	5/ 1/2017	Ψ		Ψ					233,333	Ψ	1.00	Ψυ	,,,,,,,
William J. Regan	N/A	\$	_	\$	_	_	_	_	_	\$	_	\$	— (b)

- (a) The threshold amount reflects the possibility that no cash bonus awards will be payable. The maximum amount reflects the cash bonus awards payable if the Board of Directors, in their discretion, awards the maximum cash bonus.
- (b) Mr. Klima and Mr. Regan separated from the Company during 2017, and as such will not receive a cash bonus related to fiscal 2017.
- (c) These stock options vest when both of the following conditions have been met: May 4, 2017 and a closing market price of the Company's common stock of at least \$0.85, 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: December 31, 2017 and a closing market price of the Company's common stock of at least \$1.00, and expire on the tenth anniversary of the date of grant.
- (e) These stock options vest when both of the following conditions have been met: December 31, 2018 and a closing market price of the Company's common stock of at least \$1.25, 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, 2017.

# **Outstanding Equity Awards Table at Fiscal 2017 Year-End**

		Option .	Award	s			Stock Awards							
	Underlying	of Securities g Unexercised ons (#)					Number	Market Value of Shares of		ity Incentive an Awards				
Named Executive Officer	Exercisable	Unexercisable	Opti Exerc Pric	eise	Option Expiration Date	Note	Number of Shares of Stock that Have Not Vested	Stock that Have Not Vested	Number of Unearned Shares	Market Value of Unearned Shares	Note_			
Michael M. Goldberg, M.D.	_	5,000,000	\$ 1	.00	9/22/2026	(m)								
Frederick O. Cope, Ph.D.	50,000 75,000 120,000 127,000 145,000 99,750 108,000 58,510	33,250 54,000	\$ 1 \$ 3 \$ 3 \$ 1 \$ 1	.10 .90 3.28 3.08 .77 .65	2/16/2019 10/30/2019 12/21/2020 2/17/2022 2/15/2023 1/28/2024 3/26/2025 2/25/2026	(a) (b) (c) (e) (f) (g) (i) (j)								
Thomas J. Klima (q)														
Jed A. Latkin	45,000 20,000 — —	333,334 333,333 333,333	\$ 1 \$ 0 \$ 0		4/20/2026 10/14/2026 5/4/2027 5/4/2027 5/4/2027	(k) (l) (n) (o) (p)								
William J. Regan (r)	20,000 84,000 100,000 63,750 18,750 110,000 52,405	21,250 6,250 55,000	\$ 3 \$ 3 \$ 1 \$ 1 \$ 1	.77 .50 .65	7/1/2021 2/17/2022 2/15/2023 1/28/2024 12/17/2024 3/26/2025 2/25/2026	(d) (e) (f) (g) (h) (i) (j)			,					

- (a) Options were granted 2/16/2009 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (b) Options were granted 10/30/2009 and vested as to one-third on each of the first three anniversaries of the date of grant.
- (c) Options were granted 12/21/2010 and vested as to one-fourth on each of the first four anniversaries of the date of grant.
- (d) Options were granted 7/1/2011 and vested as to one-fourth at the end of each of the first four quarters following the date of grant.
- (e) Options were granted 2/17/2012 and vested as to one-fourth on each of the first four anniversaries of the date of grant.
- (f) Options were granted 2/15/2013 and vested as to one-fourth on each of the first four anniversaries of the date of grant.
- (g) Options were granted 1/28/2014 and vest as to one-fourth on each of the first four anniversaries of the date of grant.
- (h) Options were granted 12/17/2014 and vest as to one-fourth on the date of grant, and one-fourth on January 28th of 2016, 2017 and 2018.
- (i) Options were granted 3/26/2015 and vest as to one-third on each of the first three anniversaries of the date of grant.
- (j) Options were granted 2/25/2016 and vested immediately. Options were granted in lieu of cash payment for a portion of the 2015 bonus payable to certain executive officers, calculated based on the Black-Scholes value of the options on the date of grant.
- (k) Options were granted 4/20/2016 and vested as to one-sixth on the 20th day of each of the first six months following the date of grant.
- (1) Options were granted 10/14/2016 and vested as to one-half on the 20th day of each of the first two months following the date of grant.
- (m) Options were granted 9/22/2016 and vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, subject to stockholder approval of a new Stock Incentive Plan.
- (n) Options were granted 5/4/2017 and vest 100% when both of the following conditions have been met: May 4, 2017 and a closing

- market price of the Company's common stock of at least \$0.85.
- (o) Options were granted 5/4/2017 and vest 100% when both of the following conditions have been met: December 31, 2017 and a closing market price of the Company's common stock of at least \$1.00.
- (p) Options were granted 5/4/2017 and vest 100% when both of the following conditions have been met: December 31, 2018 and a closing market price of the Company's common stock of at least \$1.25.
- (q) Mr. Klima separated from the Company effective March 8, 2017. All of Mr. Klima's unexercised stock options expired on June 6, 2017.
- (r) Mr. Regan separated from the Company effective June 30, 2017. All of Mr. Regan's stock options, if not exercised, will expire on the earlier of ten years following the date of grant or June 30, 2022.

# 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 2017.

# Options Exercised and Stock Vested Table for Fiscal 2017

	Option	Option Awards				ds	
Named Executive Officer	Number of Shares Acquired on Exercise	Valu Realize Exercis	d on	Number of Shares Acquired on Vesting		Value Realized on esting (a)	Note
Michael M. Goldberg, M.D.	_	\$	_	28,000	\$	12,572	(b)
Frederick O. Cope, Ph.D.	_	\$	_	50,000	\$	25,450	(c)
Thomas J. Klima	_	\$	_	_	\$	_	
Jed A. Latkin	_	\$	_	_	\$	_	
William J. Regan	_	\$	_	_	\$	_	

- (a) Computed using the fair market value of the stock on the date prior to or the date of exercise or vesting, as appropriate, less the purchase price of the stock, in accordance with our normal practice.
- (b) On April 20, 2017, 28,000 shares of Dr. Goldberg's restricted stock vested in accordance with the terms of his restricted stock agreement. The market price on the last trading day prior to the vesting date was \$0.45 per share. This restricted stock was granted in connection with Dr. Goldberg's service on the Company's Board of Directors.
- (c) On April 25, 2017, the CNG Committee vested 50,000 shares of Dr. Cope's restricted stock upon determining that the vesting event was unattainable due to changes in the Company's development programs. The market price on the last trading day prior to the vesting date was \$0.46 per share.

### Compensation of Non-Employee Directors

Each non-employee director received an annual cash retainer of \$50,000 during the fiscal year ended December 31, 2017. The Chairman of the Company's Board of Directors received an additional annual retainer of \$30,000, the Chairman of the Audit Committee received an additional annual retainer of \$10,000, and the Chairman of the CNG Committee received an additional annual retainer of \$7,500 for their services in those capacities during 2017. We also reimbursed non-employee directors for travel expenses for meetings attended during 2017.

Each non-employee director also received 50,000 shares of restricted stock and 50,000 options to purchase stock at \$0.75 per share during 2017 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. In April 2017, the CNG Committee vested 17,000 shares of restricted stock held by Dr. Rowinsky after determining that the vesting events would never occur due to changes in the Company's development programs.

The aggregate number of equity awards outstanding at February 28, 2018 for each Director is set forth in the footnotes to the beneficial ownership table provided in Part III, Item 12 of this Form 10-K. Directors who are also officers or employees of Navidea do not receive any compensation for their services as directors.

The following table sets forth certain information concerning the compensation of non-employee Directors for the fiscal year ended December 31, 2017.

Name	(a) Fees Earned or Paid in Cash or Stock		(b),(c) Option Awards		(d),(e) Stock Awards			All Other Compensation	Total Compensation	
Anthony S. Fiorino, M.D., Ph.D. (f)	\$	39,375	\$	12,793	\$	25,450	\$		\$	77,618
Mark I. Greene, M.D., Ph.D., FRCP		53,064		12,793		25,450		_		91,307
Y. Michael Rice		62,500		12,793		25,450		_		100,743
Eric K. Rowinsky, M.D.		90,000		12,793		25,450		_		128,243

- (a) Amount represents fees earned during the fiscal year ended December 31, 2017 (i.e., the year to which the service relates). Quarterly retainers and meeting attendance fees are paid during the quarter following the quarter in which they are earned.
- (b) Amount represents the aggregate grant date fair value in accordance with FASB ASC Topic 718.
- (c) During the year ended December 31, 2017, the non-employee directors were issued an aggregate of 200,000 options to purchase common stock which vest as to 100% of the shares on the first anniversary of the date of grant. At December 31, 2017, the non-employee directors held an aggregate of 223,764 options to purchase common stock. Dr. Rowinsky held 123,764 options, and Dr. Greene and Mr. Rice each held 50,000 options to purchase shares of common stock.
- (d) Amount represents the aggregate grant date fair value in accordance with FASB ASC Topic 718.
- (e) During the year ended December 31, 2017, the non-employee directors were issued an aggregate of 200,000 shares of restricted stock which vest as to 100% of the shares on the first anniversary of the date of grant. At December 31, 2017, the non-employee directors held an aggregate of 150,000 shares of unvested restricted stock. Drs. Greene and Rowinsky, and Mr. Rice, each held 50,000 shares of unvested restricted stock.
- (f) Dr. Fiorino resigned from the Board of Directors effective October 9, 2017. His unvested stock options and restricted stock were forfeited upon his resignation.

### 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, 2017, 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	Number of Securities Remaining Available for Issuance Under Equity Compensation of Plans (Excluding Securities Reflected in Column (1))
Equity compensation plans approved by security holders (a)	3,687,679	\$ 1.5	0 2,123,153
Equity compensation plans not approved by security holders (b)			
Total	3,687,679	\$ 1.5	0 2,123,153

- (a) Our stockholders ratified the 2014 Stock Incentive Plan (the "2014 Plan") at the 2014 Annual Meeting of Stockholders held on July 17, 2014. The total number of shares available for awards under the 2014 Plan shall not exceed 5,000,000 shares, plus any shares subject to outstanding awards granted under prior plans and that expire or terminate for any reason. Although instruments are still outstanding under the Fourth Amended and Restated 2002 Stock Incentive Plan (the "2002 Plan"), the plan has expired and no new grants may be made from it. The total number of securities to be issued upon exercise of outstanding options includes 2,327,065 issued under the 2014 Plan and 1,360,614 issued under the 2002 Plan.
- (b) In connection with Dr. Goldberg's appointment as Chief Executive Officer of the Company on September 22, 2016, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of a new Stock Incentive Plan. If approved, these stock options will vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant.

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

The following table sets forth, as of February 28, 2018, 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.

	Number of Shares		Percent
Beneficial Owner	Beneficially Owned (*)		of Class (**)
Frederick O. Cope, Ph.D.	1,243,172	(a)	— (l)
Michael M. Goldberg, M.D.	5,921,023	(b)	3.6%
Mark I. Greene, M.D., Ph.D., FRCP	57,244	(c)	— (l)
Thomas J. Klima	_	(d)	— (l)
Jed A. Latkin	115,159	(e)	— (l)
William J. Regan	674,382	(f)	— (l)
Y. Michael Rice	_	(g)	— (l)
Eric K. Rowinsky, M.D.	315,210	(h)	— (l)
All directors and executive officers as a group (6 persons)	7,651,808	(i)(m)	4.7%
Cardinal Health, Inc.	10,000,000	(j)	6.1%
Platinum-Montaur Life Sciences, LLC	16,262,120	(k)	9.9%

- (\*) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission which generally attribute beneficial ownership of securities to persons who possess sole or shared voting power and/or investment power with respect to those securities. Unless otherwise indicated, voting and investment power are exercised solely by the person named above or shared with members of such person's household.
- (\*\*)Percent of class is calculated on the basis of the number of shares outstanding on February 28, 2018, plus the number of shares the person has the right to acquire within 60 days of February 28, 2018.
- (a) This amount includes 870,510 shares issuable upon exercise of options which are exercisable within 60 days and 22,776 shares in Dr. Cope's account in the 401(k) Plan.
- (b) This amount does not include 5,000,000 shares issuable upon exercise of options which are not exercisable within 60 days and are subject to stockholder approval of a new Stock Incentive Plan.
- (c) This amount does not include 100,000 shares of unvested restricted stock and 100,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (d) Mr. Klima separated from the Company effective March 8, 2017. All of Mr. Klima's unexercised stock options expired on June 6, 2017.
- (e) This amount includes 65,000 shares issuable upon exercise of options which are exercisable within 60 days, but does not include 1,000,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (f) Mr. Regan separated from the Company effective June 30, 2017. This amount is based on Mr. Regan's most recent SEC ownership filings as well as the Company's best knowledge and belief. This amount includes 531,405 shares issuable upon exercise of options which are exercisable within 60 days and 13,822 shares in Mr. Regan's account in the 401(k) Plan.
- (g) This amount does not include 100,000 shares of unvested restricted stock and 100,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (h) This amount includes 73,764 shares issuable upon exercise of options which are exercisable within 60 days, but it does not include 100,000 shares of unvested restricted stock and 100,000 shares issuable upon exercise of options which are not exercisable within 60 days.
- (i) This amount includes 1,009,274 shares issuable upon exercise of options which are exercisable within 60 days, and 22,776 shares held in the 401(k) Plan on behalf of certain officers, but it does not include 300,000 shares of unvested restricted stock, 1,300,000 shares issuable upon the exercise of options which are not exercisable within 60 days, and 5,000,000 shares issuable upon the exercise of options which are not exercisable within 60 days and are subject to stockholder approval of a new Stock Incentive Plan. The Company's 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 143,219 shares of common stock.
- (j) The number of shares beneficially owned is based on a Schedule 13G filed by Cardinal Health, Inc. with the SEC on March 13, 2017. This amount includes 10,000,000 shares of common stock issuable upon exercise of Series NN warrants at an exercise price of \$1.50 per share. The address of Cardinal Health, Inc. is 7000 Cardinal Place, Dublin, OH 43017.
- (k) The number of shares beneficially owned is based on a Schedule 13D/A filed by Platinum and certain of its affiliates with the Securities and Exchange Commission on June 28, 2016. This amount includes (i) 13,964,519 shares of our common stock, and (ii) 2,297,601 shares of common stock issuable upon exercise of Series LL warrants (the "Series LL Warrants") at an exercise price of \$0.01 per share. The Series LL Warrants provide that the holder may not exercise any portion of the warrants to the extent that such exercise would result in the holder and its affiliates together beneficially owning more than 9.99% of the outstanding shares of common stock, except on 61 days' prior written notice to Navidea that the holder waives such limitation (the blocker). Accordingly, this amount excludes 2,067,679 shares of common stock underlying the Series LL Warrants that are subject to the blocker. The address of Platinum is c/o Otterbourg P.C., 230 Park Avenue, New York, NY 10169.
- (1) Less than one percent.
- (m) The address of all directors and executive officers is c/o Navidea Biopharmaceuticals, Inc., 4995 Bradenton Avenue, Suite 240, Dublin, OH 43017.

### Item 13. Certain Relationships and Related Transactions, and Director Independence

# Certain Relationships and Related Transactions

We adhere to our Code of Business Conduct and Ethics, which states that no director, officer or employee of Navidea should have any personal interest that is incompatible with the loyalty and responsibility owed to our Company. We adopted a written policy regarding related party transactions in December 2015. When considering whether to enter into or ratify a related party transaction, the Audit Committee considers a variety of factors including, but not limited to, the nature and type of the proposed transaction, the potential value of the proposed transaction, the impact on the actual or perceived independence of the related party and the potential value to the Company of entering into such a transaction. All proposed transactions with a potential value of greater than \$120,000 must be approved or ratified by the Audit Committee.

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

Dr. Michael Goldberg, our 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. The Company was informed by PPVA that it was the owner of additional amounts owed on the Platinum-Montaur loan. PPVA claims a balance of approximately \$1.9 million was due upon closing of the Asset Sale. That amount is also subject to competing claims of ownership by Dr. Michael Goldberg, the Company's President and Chief Executive Officer. The Company has not yet paid the balance to anyone, as ownership is subject to dispute.

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of \$1,914,827.22 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement. Said action was removed to the United States District of New York on December 6, 2017. An initial pretrial conference was held on January 26, 2018. At the conference the Court stayed the deadline for the Company to answer or otherwise respond to the complaint. The Court also directed the parties to engage in informal jurisdictional discovery and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss is due on April 6, 2018. The Court also referred the case to a settlement conference, which has been scheduled for April 30, 2018. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

If Dr. Goldberg is determined to be the owner of the remaining debt under the Platinum Loan Agreement, he has agreed to not require repayment by the Company of any debt transferred to him until the original maturity date of September 30, 2021, and has agreed to release any financial covenants and securitization requirements. Pursuant to a settlement agreement, dated as of June 16, 2016, among the Company, PPVA, Platinum-Montaur and others, Platinum agreed to forgive interest owed on its credit facility with the Company in an amount equal to 6%, effective July 1, 2016, making the effective annual interest rate on the Platinum debt 8.125% as of December 31, 2017.

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

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

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

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

During 2017, the largest aggregate amount of principal outstanding under the Platinum credit facility was \$9.6 million, and as of December 31, 2017, the amount of principal outstanding was \$2.0 million.

### 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. Greene and Rowinsky, and Mr. Rice, meet the independence requirements. The Board had also concluded that Anthony S. Fiorino, M.D., Ph.D. was independent during the time he served as a director until his departure in October 2017.

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

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

Audit-Related Fees. No fees were billed by Marcum LLP for audit-related services for the 2017 or 2016 fiscal years.

Tax Fees. No fees were billed by Marcum LLP for tax-related services for the 2017 or 2016 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 2017 or 2016 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 preapproval 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 F	inancial Statements	are included in this	Annual Report of	n Form 10-K	on the pages	indicated below:
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Report of Independent Registered Public Accounting Firm – Marcum LLP	F-2
Report of Independent Registered Public Accounting Firm – BDO USA, LLP	F-3
Consolidated Balance Sheets as of December 31, 2017 and 2016	F-4
Consolidated Statements of Operations for the years ended December 31, 2017, 2016 and 2015	F-5
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2017, 2016 and 2015	F-7
Consolidated Statements of Cash Flows for the years ended December 31, 2017, 2016 and 2015	F-9
Notes to the Consolidated Financial Statements	F-10

(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

- Amended and Restated Certificate of Incorporation of Navidea Biopharmaceuticals, Inc., as corrected February 18, 1994, and amended June 27, 1994, July 25, 1995, June 3, 1996, March 17, 1999, May 9, 2000, June 13, 2003, July 29, 2004, June 22, 2005, November 20, 2006, December 26, 2007, April 30, 2009, July 27, 2009, August 2, 2010, January 5, 2012, June 26, 2013 and August 18, 2016) (filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K filed March 31, 2017, and incorporated therein by reference).
- 3.2 Amended and Restated By-Laws dated July 21, 1993, as amended July 18, 1995, May 30, 1996, July 26, 2007, and November 7, 2013 (filed as Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed November 12, 2013, and incorporated herein by reference).
- 4.1 <u>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).</u>
- 10.1 Supply and Distribution Agreement, dated November 15, 2007, between the Company and Cardinal Health 414, LLC (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 21, 2007).
- Manufacture and Supply Agreement, dated November 30, 2009, between the Company and Reliable Biopharmaceutical
  Corporation (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Commission) (incorporated by reference to Exhibit 10.1 to the Company's June 30, 2010 Form 10-Q).
- 10.3 Asset Purchase Agreement, dated May 24, 2011, between Devicor Medical Products, Inc. and the Company (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the SEC) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed July 19, 2011).
- 10.4 License Agreement, dated December 9, 2011, between AstraZeneca AB and the Company (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the 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).
- 10.5 <u>Loan Agreement, dated July 25, 2012, between the Company and Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 31, 2012).</u>
- 10.6 Promissory Note, dated July 25, 2012, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 31, 2012).
- Form of Employment Agreement between the Company and each of Dr. Frederick O. Cope and Mr. Brent L. Larson. This agreement is one of two substantially identical employment agreements and is accompanied by a schedule which identifies material details in which each individual agreement differs from the form filed herewith (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 7, 2013).
- Schedule identifying material differences between the employment agreements incorporated by reference as Exhibit 10.4 to this Annual Report on Form 10-K (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 7, 2013).
- Amendment to Loan Agreement, dated June 25, 2013, between Navidea Biopharmaceuticals, Inc. and Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed June 28, 2013).
- 10.10 Amended and Restated Promissory Note, dated June 25, 2013, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed June 28, 2013).

Exhibit Number	Exhibit Description
10.11	Series HH Warrant to purchase common stock of Navidea Biopharmaceuticals, Inc. issued to GE Capital Equity Investments, Inc., dated June 25, 2013 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 28, 2013).
10.12	Series HH Warrant to purchase common stock of Navidea Biopharmaceuticals, Inc. issued to MidCap Financial SBIC, LP, dated June 25, 2013 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 28, 2013).
10.13	Office Lease, dated August 29, 2013, by and between Navidea Biopharmaceuticals, Inc. and BRE/COH OH LLC (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the 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).
10.14	Manufacturing Services Agreement, dated September 9, 2013, by and between Navidea Biopharmaceuticals, Inc. and OSO BioPharmaceuticals Manufacturing, LLC (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the U.S. Securities and Exchange Commission) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 12, 2013).
10.15	Director Agreement, dated November 13, 2013, by and between Navidea Biopharmaceuticals, Inc. and Michael M. Goldberg, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 19, 2013).
10.16	Second Amendment to Loan Agreement, dated March 4, 2014, between Navidea Biopharmaceuticals, Inc. and Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed March 7, 2014).
10.17	Second Amended and Restated Promissory Note, dated March 4, 2014, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed March 7, 2014).
10.18	Form of Series KK Warrants to purchase common stock of Navidea Biopharmaceuticals, Inc. issued to Oxford Finance LLC on March 4, 2014 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed March 7, 2014).
10.19	Amended and Restated License Agreement, dated July 14, 2014, between the Company and the Regents of the University of California (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the U.S. Securities and Exchange Commission) (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed August 11, 2014).
10.20	Termination of License Agreement, dated July 14, 2014, between the Company and the Regents of the University of California (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed August 11, 2014).
10.21	License Agreement, dated July 14, 2014, between the Company and the Regents of the University of California (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the 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).
10.22	Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan, adopted July 17, 2014 and amended March 3, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed May 11, 2015). ^
10.23	Form of Stock Option Agreement under the Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed November 10, 2014).
10.24	Form of Restricted Stock Award and Agreement under the Navidea Biopharmaceuticals, Inc. 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 10, 2014). ^
10.25	Employment Agreement, dated October 13, 2014, between Navidea Biopharmaceuticals, Inc. and Ricardo J. Gonzalez (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 15, 2014).
10.26	Stock Option Agreement, dated October 13, 2014, between Navidea Biopharmaceuticals, Inc. and Ricardo J. Gonzalez (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed October 15, 2014).

Exhibit Number	Exhibit Description
10.27	Securities Exchange Agreement, dated November 12, 2014, by and between Navidea Biopharmaceuticals, Inc. and Platinum
10.27	Partners Value Arbitrage Fund, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 13, 2014).
10.28	Employment Agreement between the Company and Thomas J. Klima, dated January 1, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed August 10, 2015).^
10.29	Employment Agreement between the Company and Michael Tomblyn, M.D., dated January 1, 2015 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed August 10, 2015).^
10.30	Securities Exchange Agreement dated as of March 11, 2015 among Macrophage Therapeutics, Inc., Platinum-Montaur Life Sciences, LLC and Michael Goldberg, M.D. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed May 11, 2015).
10.31	Navidea Biopharmaceuticals, Inc. 2015 Cash Bonus Plan adopted March 26, 2015 (incorporated by reference to the Company's Current Report on Form 8-K filed April 1, 2015). ^
10.32	Termination Agreement, dated April 21, 2015, by and between Navidea Biopharmaceuticals, Inc. and Alseres Pharmaceuticals, Inc. (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the U.S. Securities and Exchange Commission) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 27, 2015).
10.33	Term Loan Agreement, dated as of May 8, 2015, by and among Navidea Biopharmaceuticals, Inc., as borrower, Macrophage Therapeutics, Inc. as guarantor, and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as lenders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed October 9, 2015).
10.34	Security Agreement, dated as of May 15, 2015 among Navidea Biopharmaceuticals, Inc., as borrower, Macrophage Therapeutics, Inc. as guarantor, and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as lenders, and Capital Royalty Partners II L.P., as control agent (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 15, 2015).
10.35	Subordination Agreement, dated as of May 8, 2015, among Platinum-Montaur Life Sciences, LLC, as subordinated creditor, Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as senior creditors, and Capital Royalty Partners II L.P., as senior creditor agent, and consented to by Navidea Biopharmaceuticals, Inc. as borrower (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 15, 2015).
10.36	Third Amendment to Loan Agreement, dated as of May 8, 2015, by and between Navidea Biopharmaceuticals, Inc, as borrower, and Platinum-Montaur Life Sciences, LLC, as lender (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed May 15, 2015).
10.37	Third Amended and Restated Promissory Note, dated May 8, 2015, made by Navidea Biopharmaceuticals, Inc. in favor of Platinum-Montaur Life Sciences LLC (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed May 15, 2015).
10.38	Securities Exchange Agreement, dated as of August 20, 2015, among the Company, Montsant Partners LLC and Platinum Partners Value Arbitrage Fund, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 26, 2015).
10.39	Form of Series LL Warrant issued to Montsant Partners LLC and Platinum Partners Value Arbitrage Fund, L.P. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 26, 2015).
10.40	Amendment 1 to Term Loan Agreement by and among Navidea Biopharmaceuticals, Inc., as borrower, and Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P. and Parallel Investment Opportunities Partners II L.P., as lenders, dated as of December 23, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 11, 2016).
10.41	Agreement dated as of March 14, 2016 by and among the Company, Platinum Partners Value Arbitrage Fund L.P., Platinum Partners Liquid Opportunity Master Fund L.P., Platinum-Montaur Life Sciences, LLC, Platinum Management (NY) LLC, Platinum Liquid Opportunity Management (NY) LLC and Mark Nordlicht (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 18, 2016).

Exhibit Number	Exhibit Description
10.42	Director Agreement, dated March 15, 2016, by and between Navidea Biopharmaceuticals, Inc. and Mark I. Greene, M.D., Ph.D., FRCP (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed March 29, 2016).
10.43	Director Agreement, dated March 17, 2016, by and between Navidea Biopharmaceuticals, Inc. and Anthony S. Fiorino, M.D., Ph.D. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed March 29, 2016).
10.44	Form of Director Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 10, 2016).
10.45	Employment Agreement, dated May 9, 2016 and effective as of April 21, 2016, between Navidea Biopharmaceuticals, Inc. and Jed A. Latkin (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed May 10, 2016). ^
10.46	Settlement Agreement, dated June 16, 2016, by and among Navidea Biopharmaceuticals, Inc., Platinum Partners Value Arbitrage Fund, L.P. and Platinum-Montaur Life Sciences, LLC, Cody Christopherson, and Hunter & Kmiec (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed June 29, 2016).
10.47	Employment Agreement, dated September 22, 2016, between Navidea Biopharmaceuticals, Inc. and Michael M. Goldberg, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 27, 2016). ^
10.48	Asset Purchase Agreement, dated November 23, 2016, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 30, 2016).
10.49	Global Settlement Agreement dated March 3, 2017 by and among Navidea Biopharmaceuticals, Inc., Cardinal Health 414, LLC, Macrophage Therapeutics, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II (Cayman), L.P., Capital Royalty Partners II — Parallel Fund "A" L.P., Parallel Investment Opportunities Partners II L.P. and Capital Royalty Partners II — Parallel Fund "B" (Cayman) L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 8, 2017).
10.50	License-Back Agreement, dated March 3, 2017, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed March 8, 2017).
10.51	Warrant, dated March 3, 2017, issued to Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed March 8, 2017).
10.52	Warrant, dated March 3, 2017, issued to The Regents of the University of California (San Diego) (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed March 8, 2017).
10.53	Amended and Restated License Agreement, dated March 3, 2017, between Navidea Biopharmaceuticals, Inc. and The Regents of the University of California (San Diego) (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission) (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed March 8, 2017).
10.54	Employment Agreement, dated May 4, 2017, between Navidea Biopharmaceuticals, Inc. and Jed A. Latkin (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed May 10, 2017).^
21.1	Subsidiaries of the registrant.*
23.1	Consent of Marcum LLP.*
23.2	Consent of BDO USA, LLP.*
24.1	Power of Attorney.*
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.*

# Exhibit Number Exhibit Description

Number	Exhibit Description
32.2	Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.*
101.INS	XBRL Instance Document *
101.SCH	XBRL Taxonomy Extension Schema Document *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document *
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *
	XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document *

Management contract or compensatory plan or arrangement. Filed herewith.

# **SIGNATURES**

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

Dated: March 15, 2018

# NAVIDEA BIOPHARMACEUTICALS, INC.

(the Company)

By:/s/ Michael M. Goldberg

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

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

Signature	Title	Date
/s/ Michael M. Goldberg Michael M. Goldberg, M.D.	Director, President and Chief Executive Officer (principal executive officer)	March 15, 2018
/s/ Jed A. Latkin* Jed A. Latkin	Chief Operating Officer and Chief Financial Officer (principal financial officer and principal accounting officer)	March 15, 2018
/s/ Eric K. Rowinsky* Eric K. Rowinsky, M.D.	_ Chairman, Director	March 15, 2018
Claudine E. Bruck, Ph.D.	_ Director	
/s/ Mark I. Greene* Mark I. Greene, M.D., Ph.D., FRCP	_ Director	March 15, 2018
/s/ Y. Michael Rice* Y. Michael Rice	_ Director	March 15, 2018
*By: /s/ Michael M. Goldberg Michael M. Goldberg, M.D., Attorney-	in-fact	
	85	

# SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# NAVIDEA BIOPHARMACEUTICALS, INC.

# FORM 10-K ANNUAL REPORT

As of December 31, 2017 and 2016 and for Each of the Three Years in the Period Ended December 31, 2017

# FINANCIAL STATEMENTS

# NAVIDEA BIOPHARMACEUTICALS, INC. and SUBSIDIARIES

# **Index to Financial Statements**

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### 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, 2017 and 2016, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2017 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, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2017, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in 2013 and our report, dated March 15, 2018, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

The financial statements of Navidea Biopharmaceuticals, Inc. as of and for the year ended December 31, 2015, were audited by other auditors whose report dated March 23, 2016 expressed an unmodified opinion on those financial statements. As discussed in Notes 1 and 3 to the December 31, 2017 financial statements, on March 3, 2017, the Company completed its sale of certain assets to Cardinal Health 414, LLC. The Company has adjusted its 2016 and 2015 financial statements to retrospectively apply discontinued operations reporting related to the sale of certain assets to Cardinal Health 414, LLC that occurred in 2017. The other auditors reported on the 2015 financial statements before the retrospective adjustment.

As part of our audits of the 2017 and 2016 financial statements, we also audited the adjustments to the 2015 financial statements to retroactively apply discontinued operations reporting related to the sale of certain assets to Cardinal Health 414, LLC that occurred in 2017 as described in Notes 1 and 3. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review or apply any procedures to Navidea Biopharmaceuticals Inc.'s 2015 financial statements other than with respect to the discontinued operations treatment and, accordingly, we do not express an opinion or any other form of assurance on the 2015 financial statements as a whole.

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

/s/ Marcum LLP

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

New Haven, CT March 15, 2018

### Report of Independent Registered Public Accounting Firm

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

We have audited, before the effects of the retrospective adjustments for the discontinued operations described in Note 3 to the consolidated financial statements, the accompanying consolidated statements of operations, comprehensive income (loss), stockholders' deficit, and cash flows of Navidea Biopharmaceuticals, Inc. for the year ended December 31, 2015 (the 2015 financial statements before the effects of the retrospective adjustments discussed in Note 3 to the consolidated financial statements are not presented herein). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and the significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above, before the effects of the retrospective adjustments for the discontinued operations described in Note 3 to the consolidated financial statements, present fairly, in all material respects, the results of operations and cash flows of Navidea Biopharmaceuticals, Inc. for the year ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to the retrospective adjustments for the discontinued operations described in Note 3 to the consolidated financial statements and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by Marcum LLP.

/s/ BDO USA, LLP

Chicago, Illinois March 23, 2016

# Navidea Biopharmaceuticals, Inc. and Subsidiaries Consolidated Balance Sheets

	D	ecember 31, 2017	D	ecember 31, 2016
ASSETS				
Current assets:				
Cash and cash equivalents	\$	2,795,006	\$	1,539,325
Restricted cash		_		5,001,253
Available-for-sale securities		1,797,604		_
Accounts and other receivables		8,137,872		203,016
Inventory, net		_		96,208
Prepaid expenses and other		1,101,923		842,220
Assets associated with discontinued operations, current				3,144,247
Total current assets		13,832,405		10,826,269
Property and equipment		1,206,058		3,232,372
Less accumulated depreciation and amortization		969,357		2,051,787
Property and equipment, net		236,701		1,180,585
Patents, trademarks and license agreements		480,404		146,685
Less accumulated amortization		22,248		
Patents, trademarks and license agreements, net		458,156		146,685
Guaranteed earnout receivable		4,809,376		
Other assets		1,444,798		202,882
Assets associated with discontinued operations				105,255
Total assets	\$	20,781,436	\$	12,461,676
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	Ť	.,,	Ť	, , ,, , ,
Current liabilities:				
Accounts payable	\$	855,043	\$	5,165,385
Accrued liabilities and other	Ψ	1,857,848	Ψ	7,872,893
Notes payable, current		2,353,639		51,957,913
Terminated lease liability, current		107,215		-
Accrued loss contingency		2,887,566		_
Liabilities associated with discontinued operations, current		7,092		4,865,597
Total current liabilities	_	8,068,403	_	69,861,788
Notes payable				9,641,179
Terminated lease liability		588,092		,,o11,177 —
Other liabilities		76,611		624,922
Outer natifices		70,011		02 1,722
Total liabilities		8,733,106		80,127,889
Commitments and contingencies (Note 16)		, , , ,		, , , , , , , , , , , , , , , , , , ,
Stockholders' equity (deficit):				
Preferred stock; \$.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at December 31, 2017 and 2016		_		_
Common stock; \$.001 par value; 300,000,000 shares authorized; 162,206,646 and 155,762,729				
shares issued and outstanding at December 31, 2017 and 2016, respectively		162,207		155,763
Additional paid-in capital		331,128,787		326,564,148
Accumulated deficit		(319,908,968)		(394,855,034)
Accumulated other comprehensive loss		(2,396)		
Total Navidea stockholders' equity (deficit)		11,379,630		(68,135,123)
Noncontrolling interest		668,700		468,910
Total stockholders' equity (deficit)		12,048,330	_	(67,666,213)
<b>1</b> • • • • • • • • • • • • • • • • • • •	2	20,781,436	\$	12,461,676
Total liabilities and stockholders' equity (deficit)	\$	20,781,430	\$	12,401,0/0

See accompanying notes to consolidated financial statements.

# Navidea Biopharmaceuticals, Inc. and Subsidiaries Consolidated Statements of Operations

	Years Ended December 31,					
		2017		2016	2015	
Revenue:						
Tc99m tilmanocept sales revenue	\$	_	\$	39,601 \$	19,075	
Tc99m tilmanocept license revenue		100,000		1,795,625	1,133,333	
Tc99m tilmanocept royalty revenue		9,126		_	_	
Grant and other revenue		1,701,311		3,136,408	1,860,953	
Total revenue		1,810,437		4,971,634	3,013,361	
Cost of goods sold		3,651		62,260	3,226	
Gross profit		1,806,786		4,909,374	3,010,135	
Operating expenses:						
Research and development		4,513,842		7,138,080	10,562,729	
Selling, general and administrative		11,169,951		7,920,036	10,888,146	
Total operating expenses		15,683,793		15,058,116	21,450,875	
Loss from operations		(13,877,007)		(10,148,742)	(18,440,740)	
Other income (expense):						
Interest income (expense), net		168,971		(4,866)	(1,269,916)	
Equity in loss of R-NAV, LLC				(15,159)	(305,253)	
Loss on disposal of investment in R-NAV, LLC		_		(39,732)		
Change in fair value of financial instruments		153,357		2,858,524	(614,782)	
Loss on extinguishment of debt		(4,201,668)		· · · · —	(2,440,714)	
Other, net		(33,339)		(27,919)	26,808	
Total other income (expense), net		(3,912,679)		2,770,848	(4,603,857)	
Loss before income taxes		(17,789,686)		(7,377,894)	(23,044,597)	
Benefit from income taxes		4,062,489		· · · · · ·		
Loss from continuing operations		(13,727,197)		(7,377,894)	(23,044,597)	
Discontinued operations, net of tax effect:						
Loss from discontinued operations		(490,758)		(6,931,137)	(4,518,938)	
Gain on sale		89,163,811		_		
Net income (loss)		74,945,856		(14,309,031)	(27,563,535)	
Less loss attributable to noncontrolling interest		(210)		(648)	(855)	
Deemed dividend on beneficial conversion feature of MT Preferred Stock		_		_	(46,000)	
Net income (loss) attributable to common stockholders	\$	74,946,066	\$	(14,308,383) \$	(27,608,680)	
Income (loss) per common share (basic):						
Continuing operations	\$	(0.08)	\$	(0.05) \$	(0.15)	
Discontinued operations	\$	0.55	\$	(0.04) \$	(0.03)	
Attributable to common stockholders	\$	0.47	\$	(0.09) \$	(0.18)	
Weighted average shares outstanding (basic)		161,592,569		155,422,384	151,180,222	
Income (loss) per common share (diluted):						
Continuing operations	\$	(0.08)	\$	(0.05) \$	(0.15)	
Discontinued operations	\$	0.53	\$	(0.04) \$	(0.03)	
Attributable to common stockholders	\$	0.45	\$	(0.09) \$	(0.18)	
Weighted average shares outstanding (diluted)		166,016,458		155,422,384	151,180,222	

See accompanying notes to consolidated financial statements.

# Navidea Biopharmaceuticals, Inc. and Subsidiaries Consolidated Statements of Comprehensive Income (Loss)

		Years Ended December 31,					
			2017		2016		2015
Net income (loss)		\$	74,945,856	\$	(14,309,031)	\$	(27,563,535)
Unrealized loss on available-for-sale securities			(2,396)				
Comprehensive income (loss)		\$	74,943,460	\$	(14,309,031)	\$	(27,563,535)
	F-6						

	Preferred Stock		Common	Stock	Additional Paid-In	Accumulated	Accumulated Other Compre-hensive	Non-	Total Stockholders' Equity
		Amount	Shares	Amount	Capital	Deficit	Loss	Interest	(Deficit)
Balance, January 1, 2015 Issued stock upon	4,519	\$ 4	150,200,259	\$150,200	\$323,030,301	\$(352,983,971)	\$ 1	\$ —	\$ (29,803,466)
exercise of stock options, net Issued	_	_	124,238	124	54,206	_		_	54,330
restricted stock Canceled	_	_	354,000	354	_	_		_	354
forfeited restricted stock	_	_	(158,000)	(158)	158	_		_	_
Canceled stock to pay employee tax	7								
obligations Issued stock in payment of Board	_	_	(7,645)	(7)	(12,607)	_		_	(12,614)
retainers Issued stock	_	_	90,977	91	172,878	_		_	172,969
to 401(k)			60.155	60	115.021				117.000
plan Exchanged Series B Preferred Stock for	_	_	68,157	68	117,031	_		_	117,099
warrants Extension of warrant	(4,519)	(4)	_	_	4	_		_	_
expiration date Issued	_	_	_	_	149,615	_		_	149,615
warrants in connection with advisory services									
agreement Issued stock	_	_	_	_	256,450	_		_	256,450
upon exercise of warrants	_	_	4,977,679	4,978	(4,978)	_		_	_
Stock compensation expense	· —	_	_	_	2,368,685	_		_	2,368,685
Net loss Issuance of MT Preferred	_	_	_	_	· · · –	(27,562,680)		(855)	
Stock, net of deemed dividend					(46,000)			470,413	424,413
Balance, December 31, 2015 Issued	_	_	155,649,665	155,650	326,085,743	(380,546,651)		469,558	(53,835,700)
restricted									

stock			168,000	168	_	_	_	168
Canceled								
forfeited								
restricted								
stock	—	_	(256,000)	(256)	228	_	_	(28)
Issued stock in payment of Board								
retainers		_	84,062	84	66,455	_	_	66,539
Issued stock			- ,					
to 401(k)								
Plan	_	_	67,002	67	120,733	_	_	120,800
Issued stock upon exercise of stock options, net	_	_	50,000	50	13,450	_	_	13,500
Stock			50,000	30	15,150			13,300
compensation								
expense	_	_	_	_	277,539	_	_	277,539
Net loss						(14,308,383)	(648)	(14,309,031)
Balance, December								
31, 2016	_	_	155,762,729	155,763	326,564,148	(394,855,034)	468,910	(67,666,213)

Continued on next page.

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

		ed Stock Amount	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non- controlling Interest	Total Stockholders' Equity (Deficit)
D 1	Shares	Amount	Shares	Amount	Сарітаі	Dentit	LUSS	Interest	(Deficit)
Balance, December 31, 2016	_	_	155,762,729	155,763	326,564,148	(394,855,034)	_	468,910	(67,666,213)
Issued stock in payment of			, ,	,	, ,	, , , ,		,	
Board retainers	_	_	16,406	17	10,483	_	_	_	10,500
Issued stock in payment of employee									
bonuses	_	_	710,353	710	368,632	_	_	_	369,342
Issued stock upon exercise of	l		5 411 050	5.410	40.505				54.110
warrants			5,411,850	5,412	48,707	_	_		54,119
Issued warrants in connection with Asset Sale		_			3,337,187	_	_	_	3,337,187
Issued warrants for extension of	•				2,227,107				5,557,157
license agreement	_	_			333,719	_	_	_	333,719
Issued stock to 401(k) plan	_	_	105,308	105	53,602	_	_	_	53,707
Issued restricted			, i		,				,
stock	_	_	200,000	200		_	_	_	200
Canceled forfeited									
restricted stock		_	(50,000)	(50)	50	_	_	_	_
Issued stock upon exercise of	l		50,000	50	10.050				10.100
stock options Stock	_	_	50,000	50	18,050	_	<u> </u>	_	18,100
compensation					394,209				204 200
expense Comprehensive income (loss):	_	<u> </u>	_	_	394,209	<u> </u>	<u> </u>	_	394,209
Net income	_	_	_	_	_	74,946,066	_	(210)	74,945,856
Unrealized loss on available- for-sale						, ,		,	, ,
securities		_	_	_	_	_	(2,396)	_	(2,396)
Total comprehensive							(=,= = = )		
income	_	_	_	_	_	_	_	_	74,943,460
Reclassification of funds									
invested (Note 10)	_	_	_	_	_	_	_	200,000	200,000
Balance, December 31, 2017	_	s —	162,206,646	\$162,207	\$331,128,787	\$(319,908,968)	\$ (2,396)		\$ 12,048,330

See accompanying notes to consolidated financial statements.

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

		Year Ended December 31,				
		2017		2016	201	5
Cash flows from operating activities:						
Net income (loss)	\$	74,945,856	\$	(14,309,031) \$	(27,	563,535)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:						
Depreciation and amortization of property and equipment		232,339		496,178		562,468
Amortization of patents, trademarks and license agreements		22,248		5,191		8,951
Loss on disposal and abandonment of assets		807,241		136,719		33,184
Gain on forgiveness of accounts payable		(212,656)		(85,355)		´ —
Change in inventory reserve				43,354		143,493
Amortization of debt discount and issuance costs		_		77,964		492,963
Debt discount and issuance costs written off		_		1,955,541		
Prepayment premium and debt collection fees related to long term debt		_		2,923,271		_
Compounded interest on long term debt		265,196		1,561,568	2.	048,960
Stock compensation expense		394,209		277,539		368,685
Equity in loss of R-NAV, LLC		_		15,159		305,253
Loss on disposal of investment in R-NAV, LLC		_		39,732		_
Edots on disposar of investment in 10 1411, EEC		(153,357)		(2,858,524)		614,782
Change in fair value of financial instruments		(155,557)		(2,000,021)		011,702
Loss on extinguishment of debt		4,201,668		_	2.	440,714
Issued warrants in connection with Asset Sale		3,337,187		_	,	
Extension of warrant expiration date		_		_		149,615
Issued warrants in connection with advisory services agreement		_		_		256,450
Value of stock issued to directors		10,500		66,539		172,969
Value of stock issued to employees		369,342				
Value of stock issued to 401(k) plan for employer matching contributions		53,707		120,800		117,099
Other		65		(15,159)		(63,677)
Changes in operating assets and liabilities:		05		(13,137)		(05,077)
Accounts and other receivables		(11,145,238)		1,882,855	(2	808,696)
Inventory		1,470,826		(861,274)		135,986
Prepaid expenses and other assets		(934,536)		187,379		263,915
Accounts payable		(6,017,775)		5,441,155		290,024
Accrued liabilities and other liabilities		(6,248,179)		5,351,090		282,642)
Deferred revenue		(2,315,037)		1,104,089		237,009
		59,083,606		3,556,780		076,030)
Net cash provided by (used in) operating activities  Cash flows from investing activities:		39,083,000	_	3,330,780	(19,	070,030)
Purchases of available-for-sale securities		(2.200.000)				
		(2,200,000)		<del>-</del>		
Maturities of available-for-sale securities		400,000		(1.047)		(20,001)
Purchases of equipment		(33,690)		(1,847)		(39,001)
Proceeds from sales of equipment		_		45,000		38,265
Patent and trademark costs				(110,000)		(27,092)
Payments on disposal of investment in R-NAV, LLC		_		(110,000)		_
Proceeds from disposal of investment in R-NAV, LLC	_	(1.022.600)		27,623		(25,020)
Net cash used in investing activities		(1,833,690)		(39,224)		(27,828)
Cash flows from financing activities:						
Proceeds from issuance of MT Preferred Stock and warrants		_		_		500,000
Payment of preferred stock issuance costs						(12,587)
Proceeds from issuance of common stock, net		72,419		13,640		65,975
Payment of tax withholdings related to stock-based compensation		_		_		(23,906)
Proceeds from notes payable		_		_		500,000
Payment of debt-related costs		(1,314,102)		(3,923,271)		902,487)
Principal payments on notes payable		(59,753,740)		(231,453)	(30,	333,333)
Restricted cash held for payment against debt		5,001,188		(5,001,253)		_
Payments under capital leases				(2,154)		(2,550)
Net cash (used in) provided by financing activities		(55,994,235)		(9,144,491)	20,	791,112
Net increase (decrease) in cash		1,255,681		(5,626,935)		687,254
Cash and cash equivalents, beginning of period		1,539,325		7,166,260		479,006
Cash and cash equivalents, end of period	\$	2,795,006	\$	1,539,325 \$		166,260
Cash and Cash equivalents, elld of period	Ψ	_,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Ψ	1,000,020	7,	- 55,200

See accompanying notes to 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<sup>TM</sup> platform to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care.

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Lymphoseek<sup>®</sup> (technetium Tc99m tilmanocept) injection, the first product developed and commercialized by Navidea based on the platform. Building on the success of Tc99m tilmanocept, the flexible and versatile Manocept platform acts as an engine for the design of purpose-built molecules offering the potential to be utilized across a range of diagnostic modalities, including single photon emission computed tomography ("SPECT"), positron emission tomography ("PET"), intra-operative and/or optical-fluorescence detection in a variety of disease states.

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

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

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

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.

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

From our inception through August 2011, we manufactured a line of gamma radiation detection medical devices called the neoprobe® GDS system (the "GDS Business"). We sold the GDS Business to Devicor Medical Products, Inc. ("Devicor") in August 2011. In exchange for the assets of the GDS Business, Devicor made net cash payments to us totaling \$30.3 million, assumed certain liabilities of the Company associated with the GDS Business, and agreed to make royalty payments to us of up to an aggregate maximum amount of \$20 million based on the net revenue attributable to the GDS Business through 2017. Based on the 2015 GDS Business revenue, we recorded income of \$759,000, net of taxes, in 2015 related to royalty amounts earned based on 2015 GDS Business revenue. The royalty amount of \$1.2 million was offset by \$436,000 in estimated taxes which were allocated to discontinued operations, but were fully offset by the tax benefit from our net operating loss for 2015. We did not earn or receive any such royalty payments prior to 2015 or in 2016 and 2017.

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 December 2001, we acquired Cardiosonix Ltd. ("Cardiosonix"), an Israeli company with a blood flow measurement device product line in the early stages of commercialization. In August 2009, the Company's Board of Directors decided to discontinue the operations and attempt to sell Cardiosonix. However, we were obligated to continue to service and support the Cardiosonix devices through 2013. The Company did not receive significant expressions of interest in the Cardiosonix business and it was legally dissolved in September 2017.

- b. Principles of Consolidation: Our consolidated financial statements include the accounts of Navidea and our wholly-owned subsidiaries, Navidea Biopharmaceuticals Limited and Cardiosonix Ltd, as well as those of our majority-owned subsidiary, MT. All significant inter-company accounts were eliminated in consolidation. Prior to termination of Navidea's joint venture with R-NAV, LLC ("R-NAV") in May 2016, Navidea's investment in R-NAV was being accounted for using the equity method of accounting and was therefore not consolidated. See Note 11.
- 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 4.

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

- (1) Cash, restricted cash, 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. At December 31, 2016, restricted cash represents the balance in an account that was under the control of Capital Royalty Partners II L.P. ("CRG"). See Note 13. At December 31, 2017 and 2016, approximately \$96,000 and \$894,000, respectively, of accounts payable was being disputed by the Company related to unauthorized expenditures by a former executive, which were incurred during the year ended December 31, 2016.
- (2) Notes payable: The carrying value of our debt at December 31, 2017 and 2016 primarily consists of the face amount of the notes less unamortized discounts. At December 31, 2017 and 2016, the conversion option of certain notes payable was required to be recorded at fair value. The estimated fair value of the conversion option was calculated using a Monte Carlo simulation. This valuation method includes Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. Unrealized gains and losses on the fair value of the conversion option are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations. At December 31, 2017, the fair value of the conversion option is approximately zero. At December 31, 2017, the fair value of our notes payable was approximately \$2.4 million, equal to the carrying value of \$2.4 million. At December 31, 2016, the fair value of our notes payable was approximately \$61.6 million, equal to the carrying value of \$61.6 million. See Notes 4 and 13.
- (3) Derivative liabilities: Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. Derivative liabilities totaling \$63,000 as of December 31, 2017 and 2016 were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of December 31, 2017 and 2016 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 4.

- (4) Warrants: In March 2017, in connection with the Asset Sale, the Company granted to each of Cardinal Health 414 and the University of California, San Diego, ("UCSD"), a five-year warrant to purchase up to 10 million shares and 1 million shares, respectively, of the Company's common stock at an exercise price of \$1.50 per share, each of which warrant is subject to anti-dilution and other customary terms and conditions (the "Series NN warrants"). The assumptions used to calculate fair value at the date of issuance included volatility, a risk-free rate and expected dividends. The Series NN warrants granted to Cardinal Health 414 had an estimated fair value of \$3.3 million, which was recorded as a reduction of the gain on sale in the consolidated statement of operations for the year ended December 31, 2017. The Series NN warrants granted to UCSD had an estimated fair value of \$334,000, which was recorded as an intangible asset related to the UCSD license in the consolidated balance sheet during the year ended December 31, 2017. See Note 18.
- e. Stock-Based Compensation: At December 31, 2017, we had instruments outstanding under two stock-based compensation plans; the Fourth Amended and Restated 2002 Stock Incentive Plan (the "2002 Plan") and the 2014 Stock Incentive Plan (the "2014 Plan"). Currently, under the 2014 Plan, we may grant incentive stock options, nonqualified stock options, and restricted stock awards to full-time employees and directors, and nonqualified stock options and restricted stock awards may be granted to our consultants and agents. Total shares authorized under each plan are 12 million shares and 5 million shares, respectively. Although instruments are still outstanding under the 2002 Plan, the plan has expired and no new grants may be made from it. Under both plans, the exercise price of each option is greater than or equal to the closing market price of our common stock on the date of the grant.

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

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

Stock-based payments to employees and directors, including grants of stock options, are recognized in the consolidated statement of operations based on their estimated fair values. The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. Expected volatilities are based on the Company's historical volatility, which management believes represents the most accurate basis for estimating expected future volatility under the current circumstances. Navidea uses historical data to estimate forfeiture rates. The expected term of stock options granted is based on the vesting period and the contractual life of the options. The risk-free rate is based on the U.S. Treasury yield in effect at the time of the grant. The assumptions used to calculate the fair value of stock option awards granted during the years ended December 31, 2017, 2016 and 2015 are noted in the following table:

	2017	2016	2015
Expected volatility	66% - 79%	59% - 75%	61% - 64%
Weighted-average volatility	75%	60%	62%
Expected dividends	_	_	_
Expected term (in years)	5.0 - 6.0	5.0 - 6.0	5.1 - 6.3
Risk-free rate	1.8% - 2.1%	1.2% - 1.8%	1.5% - 1.9%

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 5.

f. Cash and Cash Equivalents: Cash equivalents are highly liquid instruments such as U.S. Treasury bills, bank certificates of deposit, corporate commercial paper and money market funds which have maturities of less than 3 months from the date of purchase.

- g. Accounts and Other Receivables: Accounts and other receivables are recorded net of an allowance for doubtful accounts. We estimate an allowance for doubtful accounts based on a review and assessment of specific accounts and other receivables and write off accounts when deemed uncollectible. See Note 7.
- h. Inventory: All components of inventory are valued at the lower of cost (first-in, first-out) or net realizable value. We adjust inventory to net realizable value when the net realizable value is lower than the carrying cost of the inventory. Net realizable value is determined based on estimated sales activity and margins. We estimate a reserve for obsolete inventory based on management's judgment of probable future commercial use, which is based on an analysis of current inventory levels, estimated future sales and production rates, and estimated shelf lives. See Note 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 patents and trademarks. Intangible assets are stated at cost, less accumulated amortization. Patent costs are amortized using the straight-line method over the estimated useful lives of the patents of approximately 5 to 15 years. Patent application costs are deferred pending the outcome of patent applications. Costs associated with unsuccessful patent applications and abandoned intellectual property are expensed when determined to have no recoverable value. We evaluate the potential alternative uses of all intangible assets, as well as the recoverability of the carrying values of intangible assets, on a recurring basis.
- k. Impairment or Disposal of Long-Lived Assets: Long-lived assets and certain identifiable intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. No impairment was recognized during the years ended December 31, 2017, 2016 or 2015. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.
- Leases: Leases are categorized as either operating or capital leases at inception. Operating lease costs are recognized on a straight-line basis over the term of the lease. An asset and a corresponding liability for the capital lease obligation are established for the cost of capital leases. The capital lease obligation is amortized over the life of the lease. For build-to-suit leases, the Company establishes an asset and liability for the estimated construction costs incurred to the extent that it is involved in the construction of structural improvements or takes construction risk prior to the commencement of the lease. Upon occupancy of facilities under build-to-suit leases, the Company assesses whether these arrangements qualify for sales recognition under the sale-leaseback accounting guidance. If a lease does not meet the criteria to qualify for a sale-leaseback transaction, the established asset and liability remain on the Company's balance sheet. See Note 15.
- m. Derivative Instruments: Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated from the debt instrument and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. Derivative liabilities with expiration dates within one year are classified as current, while those with expiration dates in more than one year are classified as long term. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes.
- n. Revenue Recognition: Prior to the Asset Sale to Cardinal Health 414 in March 2017, we generated revenue primarily from sales of Lymphoseek. Our standard shipping terms are free on board (FOB) shipping point, and title and risk of loss passes to the customer upon delivery to a carrier for shipment. We generally recognize sales revenue related to sales of our products when the products are shipped. Our customers have no right to return products purchased in the ordinary course of business, however, we may allow returns in certain circumstances based on specific agreements.

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

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

Lastly, we recognized revenues from the provision of services to R-NAV and its subsidiaries through the termination of the R-NAV joint venture on May 31, 2016. See Note 11.

- 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, 2017 and 2016.

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, 2017 or 2016 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, 2017, tax years 2014-2017 remained subject to examination by federal and state tax authorities. See Note 20.

Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is that a company should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five-step process that requires companies to exercise more judgment and make more estimates than under the current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. Since the issuance of ASU 2014-09, several additional ASUs have been issued and incorporated within Topic 606 to clarify various elements of the guidance. ASU 2014-09 allows a choice of transition methods: (a) a full retrospective adoption in which the standard is applied to all of the periods presented, or (b) a modified retrospective adoption in which the standard is applied only to the most current period presented in the financial statements with a cumulative-effect adjustment reflected in retained earnings. ASU 2014-09 also requires significantly expanded disclosures regarding the qualitative and quantitative information of an entity's nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those periods.

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

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

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

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

Following the sale of the Business to Cardinal Health 414 in March 2017, we generate revenue primarily from grants to support certain of our product development programs. Such grant revenues are recognized only after expenses reimbursable under the grants have been paid. 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 will require separate assessment using the five-step process under ASU 2014-09. We adopted ASU 2014-09 along with additional related ASUs 2016-08, 2016-10, 2016-12 and 2016-20 effective January 1, 2018 using the modified retrospective method of adoption. The Company expects the adoption of ASU 2014-09 and related ASUs to result in increases in deferred revenue and accumulated deficit of approximately \$100,000.

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

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

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows – Restricted Cash*. ASU 2016-18 requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash or equivalents. Therefore, restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption in permitted, including adoption in an interim period. If an entity early adopts ASU 2016-18 in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes the interim period. We adopted ASU 2016-18 effective January 1, 2018. The Company expects the adoption of ASU 2016-18 to result in reclassification of \$5.0 million of restricted cash in the consolidated statement of cash flows for the years ended December 31, 2017 and 2016.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic* 805), *Clarifying the Definition of a Business*. ASU 2017-01 provides a screen to determine when a set of assets and activities (collectively, a "set") is not a business. The screen requires that when substantially all of the fair market value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, ASU 2017-01 (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output, and (2) removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those periods. ASU 2017-01 should be applied prospectively on or after the effective date. No disclosures are required at transition. Early adoption is permitted for certain transactions as described in ASU 2017-01. The adoption of ASU 2017-01 effective January 1, 2018 will not have a material effect on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic* 718), *Scope of Modification Accounting*. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all of the following criteria are met: (1) The fair value of the modified award is the same as the fair value of the original award immediately before the original award, is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification. (2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified. (3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. Disclosure requirements remain unchanged. ASU 2017-09 is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted as described in ASU 2017-09. The adoption of ASU 2017-09 effective January 1, 2018 will not have a material effect on our consolidated financial statements.

In September 2017, the FASB issued ASU No. 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842). ASU 2017-13 adds SEC paragraphs pursuant to an SEC Staff Announcement made in July 2017 and clarifies several issues related to transition and implementation of the covered topics, including clarification of the definition of a public business entity, the effect of a change in tax law or rates on leveraged leases, and related amendments to the eXtensible Business Reporting Language ("XBRL") taxonomy. Management is currently evaluating the impact that the adoption of ASU 2017-13 will have on our consolidated financial statements.

## 2. Liquidity

Prior to the Asset Sale to Cardinal Health 414 in March 2017, all of our material assets were pledged as collateral for our borrowings under the CRG Loan Agreement. In addition to the security interest in our assets, the CRG Loan Agreement included covenants that imposed significant requirements on us. An event of default would have entitled CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement. During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas (the "Texas Court"). 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. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of the settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59.0 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan, Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in the Texas Court to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47.0 million and no more than \$66.0 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7.0 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12.0 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59.0 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2.0 million being held in escrow pursuant to court order in the Ohio case and the \$3.0 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7.0 million letter of credit, and on March 7, 2017, CRG posted a \$12.0 million letter of credit, each as required by the Global Settlement Agreement.

The trial was held in Texas in December 2017. The Texas Court ruled that the Company's total obligation to CRG is 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 owes 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. The Company believes that this \$4.1 million should be credited against the \$7.0 million; CRG disagrees. On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the Texas Court's oversight of not explaining how to apply the \$4.1 million payment, requesting that the judgment be modified to set the supersedeas amount at \$2.9 million so that the Company can stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. The Texas Court has scheduled a hearing on the issue for March 26, 2018, however it has not yet set the amount, and enforcement of the judgment is stayed until seven days after the Texas Court does so. We currently await further action by the Texas Court. If we are ultimately required to pay an additional \$7.0 million to CRG, such payment would have a significant adverse effect on our financial position and would likely force us to curtail our planned development activities. See Note 13.

In addition, the Company previously was a party to a Loan Agreement with Platinum-Montaur Life Sciences LLC ("Platinum-Montaur"), an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P., Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, "Platinum") (the "Platinum Loan Agreement") and a Third Amended and Restated Promissory Note ("Platinum Note") given by Navidea in favor of Platinum-Montaur.

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. The Company was informed by PPVA that it was the owner of additional amounts owed on the Platinum-Montaur loan. PPVA claims a balance of approximately \$1.9 million was due upon closing of the Asset Sale. That amount is also subject to competing claims of ownership by Dr. Michael Goldberg, the Company's President and Chief Executive Officer. The Company has not yet paid the balance to anyone, as ownership is subject to dispute.

On March 2, 2017, PPCO provided the Payoff Letter. In the Payoff Letter, PPCO defined "Indebtedness" to include all amounts due under the Platinum Note, indicated that upon payment of the Payoff Amount, all "Indebtedness owed to Lender" shall have been satisfied in full, and that the "Loan Documents," which included the Platinum Loan Agreement and the Platinum Note, "shall terminate and have no further force or effect." The letter also confirmed that as of the date that payment was made by Navidea, the Receiver was providing a release and indemnification in favor of Navidea based on any claims made by any affiliate of PPCO. The Payoff Amount was paid pursuant to the Payoff Letter. The remaining balance of the Platinum Note would have matured under its terms in September 2017, however the Company has not paid the balance as it is still subject to ongoing competing claims of ownership. The Company intends to pay the balance of the debt if it is determined to be due and owing to PPVA or Dr. Goldberg.

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of \$1,914,827.22 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement. Said action was removed to the United States District of New York on December 6, 2017. An initial pretrial conference was held on January 26, 2018. At the conference the Court stayed the deadline for the Company to answer or otherwise respond to the complaint. The Court also directed the parties to engage in informal jurisdictional discovery and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss is due on April 6, 2018. The Court also referred the case to a settlement conference, which has been scheduled for April 30, 2018. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern was alleviated. Based on our current working capital and our projected cash burn, including our belief that the Company will be obligated to pay up to an additional \$2.9 million to CRG, management believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Annual Report on Form 10-K. Our projected cash burn also factors in certain cost cutting initiatives that have been implemented and approved by the board of directors, including reductions in the workforce and a reduction in facilities expenses. Additionally, we have considerable discretion over the extent of development project expenditures and have the ability to curtail the related cash flows as needed. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of non-dilutive funding, including collaborations and additional grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be supported by our revenues. We believe all of these factors are sufficient to alleviate substantial doubt about the Company's ability to continue as a going concern.

## 3. Discontinued Operations

In August 2011, the Company completed the sale of the GDS Business to Devicor. We recorded net income of \$759,000 in 2015 related to royalty amounts earned based on 2015 GDS Business revenue. The royalty amount of \$1.2 million was offset by \$436,000 in estimated taxes which were allocated to discontinued operations.

On March 3, 2017, the Company completed the sale to Cardinal Health 414 of its assets used, held for use, or intended to be used in operating its business of developing, manufacturing and commercializing a product used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer, including the Company's radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the FDA and similar indications approved by the FDA in the future, in Canada, Mexico and the United States. In exchange for the Acquired Assets, Cardinal Health 414 (i) made a cash payment to the Company at closing of approximately \$80.6 million after adjustments based on inventory being transferred and an advance of \$3.0 million of guaranteed earnout payments as part of the CRG settlement, (ii) assumed certain liabilities of the Company associated with the Product as specified in the Purchase Agreement, and (iii) agreed to make periodic earnout payments (to consist of contingent payments and milestone payments which, if paid, will be treated as additional purchase price) to the Company based on net sales derived from the purchased Product.

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

As a result of the sale of the GDS Business to Devicor and the Asset Sale to Cardinal Health 414, we reclassified certain assets and liabilities as assets and liabilities associated with discontinued operations. The following assets and liabilities have been segregated and included in assets associated with discontinued operations or liabilities associated with discontinued operations, as appropriate, in the consolidated balance sheets:

	Dec	ember 31, 2017	De	ecember 31, 2016
Accounts and other receivables	\$	_	\$	1,598,994
Inventory, net		_		1,374,618
Prepaid expenses		<u> </u>		170,635
Assets associated with discontinued operations, current		_		3,144,247
Property and equipment, net of accumulated depreciation		_		70,973
Patents and trademarks, net of accumulated amortization				34,282
Assets associated with discontinued operations, noncurrent				105,255
Total assets associated with discontinued operations	\$	_	\$	3,249,502
Accounts payable	\$	_	\$	1,957,938
Accrued liabilities		7,092		607,659
Deferred revenue				2,300,000
Liabilities associated with discontinued operations, current		7,092		4,865,597
Other liabilities				
Total liabilities associated with discontinued operations	\$	7,092	\$	4,865,597

In addition, we reported certain revenues related to the sale of the GDS Business to Devicor, as well as certain revenues and expenses related to the Asset Sale to Cardinal Health 414, to discontinued operations for all periods presented, including interest expense related to the CRG and Platinum debt obligations as required by current accounting guidance. The following amounts have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

	 Years Ended December 31,					
	2017	2016	2015			
Revenue:						
Lymphoseek sales revenue	\$ 2,917,213	\$ 16,997,497	\$ 10,235,277			
Royalties on GDS Business	_	_	1,194,660			
Grant and other revenue	 	575	669			
Total revenue	 2,917,213	16,998,072	11,430,606			
Cost of goods sold	 364,192	2,234,780	1,751,537			
Gross profit	 2,553,021	14,763,292	9,679,069			
Operating expenses:						
Research and development	383,446	1,744,496	2,225,004			
Selling, general and administrative	 961,873	5,093,529	6,369,183			
Total operating expenses	 1,345,319	6,838,025	8,594,187			
Income from discontinued operations	 1,207,702	7,925,267	1,084,882			
Interest expense	 (1,706,491)	(14,856,404)	(5,603,820)			
Income (loss) before income taxes	(498,789)	(6,931,137)	(4,518,938)			
Benefit from (provision for) income taxes	8,031					
Loss from discontinued operations	\$ (490,758)	\$ (6,931,137)	\$ (4,518,938)			

## 4. Fair Value

The Company was informed by PPVA that it was the owner of additional amounts owed on the Platinum-Montaur loan. PPVA claims a balance of approximately \$1.9 million was due upon closing of the Asset Sale. That amount is also subject to competing claims of ownership by Dr. Michael Goldberg, the Company's President and Chief Executive Officer. The Company has not yet paid the balance to anyone, as ownership is subject to dispute.

If determined to be the obligee under the Platinum Note, PPVA or Dr. Goldberg would have had the right to convert all or any portion of the unpaid principal or unpaid interest accrued on all draws under the Platinum credit facility, under certain circumstances. The Platinum embedded option to convert such debt into common stock is recorded at fair value on the consolidated balance sheets and deemed to be a derivative instrument as the amount of shares to be issued upon conversion is indeterminable. The estimated fair value of the conversion option of the Platinum Note payable is approximately \$0 and \$153,000 on December 31, 2017 and 2016, respectively, and is included in notes payable on the accompanying consolidated balance sheets. Subsequent to its maturity in September 2017, the Platinum Note no longer has an embedded conversion option.

MT issued warrants to purchase MT Common Stock with certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value on the consolidated balance sheets. The estimated fair value of the MT warrants is \$63,000 at both December 31, 2017 and 2016, is included in other liabilities on the accompanying consolidated balance sheets, and will continue to be measured on a recurring basis. See Notes 1(m) and 10.

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

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2017

	Quoted Prices in Active			
	Markets for Identical Assets and Liabilities	Significant Other Observable Inputs	Significant Unobservable Inputs (a)(b)	Balance as of December 31,
Description	(Level 1)	(Level 2)	(Level 3)	2017
Platinum conversion option	\$ —	<u> </u>	\$ —	\$ —
Liability related to MT warrants	_	_	63,000	63,000

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

	Quoted	Prices						
	in A	ctive						
	Marke	ets for	Significa	nt			В	alance as
	Iden	tical	Other		Sig	gnificant		of
	Asset	s and	Observab	ole	Uno	bservable	D	ecember
	Liabi	lities	Inputs		Inp	uts (a)(b)		31,
Description	(Lev	el 1)	(Level 2	)	(I	Level 3)		2016
Platinum conversion option	\$		\$		\$	153,357	\$	153,357
Liability related to MT warrants		_		_		63,000		63,000

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

The assumptions used in the Monte Carlo simulation as of December 31, 2016 are summarized in the following table:

	20:	<u> 16                                   </u>
Estimated volatility		76%
Expected term (in years)		4.75
Debt rate		8.125%
Beginning stock price	\$	0.64

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

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

There were no Level 1 or Level 2 liabilities outstanding at any time during the years ended December 31, 2017 and 2016. There were no transfers in or out of our Level 1 or Level 2 liabilities during the years ended December 31, 2017 and 2016. Changes in the estimated fair value of our Level 3 liabilities relating to unrealized gains (losses) are recorded as changes in fair value of financial instruments in the consolidated statements of operations. The change in the estimated fair value of our Level 3 liabilities during the years ended December 31, 2017, 2016 and 2015 was an approximate decrease of \$153,000, a decrease of \$2.9 million, and an increase of \$615,000, respectively.

## 5. Stock-Based Compensation

For the years ended December 31, 2017, 2016 and 2015, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately \$394,000, \$278,000 and \$2.4 million, respectively. We have not recorded any income tax benefit related to stock-based compensation for the years ended December 31, 2017, 2016 and 2015.

A summary of the status of our stock options as of December 31, 2017, and changes during the year then ended, is presented below:

	Year Ended December 31, 2017						
	Number of Options		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)		Aggregate Intrinsic Value	
Outstanding at beginning of year	3,380,615	\$	2.00				
Granted	1,720,000		0.71				
Exercised	(50,000)		0.36				
Canceled and forfeited	(1,362,936)		1.77				
Outstanding at end of year	3,687,679	\$	1.50	7.0	\$		_
Exercisable at end of year	1,946,445	\$	2.15	4.9	\$		

The weighted average grant-date fair value of options granted in 2017, 2016, and 2015 was \$0.19, \$0.53 and \$1.67, respectively. During 2017, 50,000 stock options with an aggregate intrinsic value of \$4,400 were exercised in exchange for issuance of 50,000 shares of our common stock, resulting in gross proceeds of \$18,100. During 2016, 50,000 stock options with an aggregate intrinsic value of \$23,000 were exercised in exchange for issuance of 50,000 shares of our common stock, resulting in gross proceeds of \$13,500. During 2015, 146,625 stock options with an aggregate intrinsic value of \$144,000 were exercised in exchange for issuance of 124,238 shares of our common stock, resulting in gross proceeds of \$66,000. In 2017, 2016, and 2015, the aggregate fair value of stock options vested during the year was \$0, \$3,000 and \$277,000, respectively.

A summary of the status of our unvested restricted stock as of December 31, 2017, and changes during the year then ended, is presented below:

	Year Ended December 31, 2017			
	Number of Shares	A <sup>r</sup> Gra	eighted verage ant-Date ir Value	
Unvested at beginning of year	207,000	\$	1.17	
Granted	200,000		0.51	
Forfeited	(50,000)		0.51	
Vested	(207,000)		1.17	
Unvested at end of year	150,000	\$	0.51	

During 2017, 2016 and 2015, 207,000, 66,000 and 333,250 shares, respectively, of restricted stock vested with aggregate vesting date fair values of \$99,000, \$63,000 and \$511,000, respectively.

In October 2017, 50,000 shares of restricted stock held by a non-employee director with an aggregate fair value of \$22,000 were forfeited as a result of his departure from the Board. During 2017, 140,000 shares of restricted stock held by non-employee directors with an aggregate fair value of \$65,000 vested as scheduled according to the terms of the restricted stock agreements. Also during 2017, 17,000 shares of restricted stock held by a non-employee director with an aggregate fair value of \$9,000, and 50,000 shares of restricted stock held by an executive officer with an aggregate fair value of \$25,000, were vested by Board action after determination that the vesting events would not occur due to changes in the Company's development programs.

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

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

During 2015, we paid minimum tax withholdings related to stock options exercised and restricted stock vested of \$24,000. No such tax withholdings were paid related to stock options exercised or restricted stock vested during 2017 or 2016. As of December 31, 2017, there was approximately \$176,000 of total unrecognized compensation cost related to stock option and restricted stock awards, which we expect to recognize over remaining weighted average vesting terms of 1.2 years. See Note 1(e).

## 6. Earnings Per Share

Basic earnings (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares and, except for periods with a loss from operations, participating securities outstanding during the period. Diluted earnings (loss) per share reflects additional common shares that would have been outstanding if dilutive potential common shares had been issued. Potential common shares that may be issued by the Company include convertible debt, convertible preferred stock, options and warrants.

The following table sets forth the reconciliation of the weighted average number of common shares outstanding used to compute basic and diluted earnings (loss) per share for the years ended December 31, 2017, 2016 and 2015:

	Year	Years Ended December 31,					
	2017	2016	2015				
Weighted average shares outstanding, basic	161,592,569	155,422,384	151,180,222				
Dilutive shares related to warrants	4,273,889	_	_				
Unvested restricted stock	150,000						
Weighted average shares outstanding, diluted	166,016,458	155,422,384	151,180,222				

Diluted earnings (loss) per common share for the years ended December 31, 2017, 2016 and 2015 excludes the effects of 14.5 million, 14.1 million and 14.6 million common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of common shares issuable upon exercise of outstanding stock options and warrants, and upon the conversion of convertible debt and convertible preferred stock.

The Company's unvested stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as "participating securities"). Therefore, the unvested stock awards are required to be included in the number of shares outstanding for both basic and diluted earnings per share calculations. However, due to our loss from continuing operations, 150,000, 207,000 and 361,000 shares of unvested restricted stock for the years ended December 31, 2017, 2016 and 2015, respectively, were excluded in determining basic and diluted loss per share because such inclusion would be anti-dilutive.

#### 7. Accounts and Other Receivables and Concentrations of Credit Risk

Accounts and other receivables at December 31, 2017 and 2016 consist of the following:

	2017	<u> </u>	2016
Guaranteed earnout receivable, current	\$ 8,0	84,392 \$	_
Trade		_	18,420
Other		53,480	184,596
Total accounts and other receivables	\$ 8,1	37,872 \$	203,016

At December 31, 2017 and 2016, approximately 99% and 0%, respectively, of net accounts and other receivables were due from Cardinal Health 414. As of December 31, 2017 and 2016, there was no allowance for doubtful accounts. We do not believe we are exposed to significant credit risk related to Cardinal Health 414 based on the overall financial strength and credit worthiness of the entity. We believe that we have adequately addressed credit risks in estimating the allowance for doubtful accounts. See Note 1(g).

Accounts and other receivables in the amount of \$1,598,994 as of December 31, 2016 have been reclassified to current assets associated with discontinued operations. See Note 3.

#### 8. Inventory

The components of net inventory at December 31, 2017 and 2016, net of reserves of \$748 and \$0, respectively, are as follows:

	 2017	2016
Materials	\$ _	\$ 94,500
Work-in-process	_	1,708
Finished goods	748	_
Reserves	 (748)	
Total inventory, net	\$ _	\$ 96,208

During 2016, we utilized \$131,000 of Tc99m tilmanocept inventory for clinical study and product development purposes. Also during 2016, we recorded obsolescence reserves of \$43,000 of Tc99m tilmanocept inventory related to specific lots that expired or were nearing product expiry and therefore were no longer expected to be sold. See Note 1(h).

Inventory in the amount of \$1,374,618 as of December 31, 2016 has been reclassified to current assets associated with discontinued operations. See Note 3.

### 9. Property and Equipment

The major classes of property and equipment are as follows:

	Useful Life (in		
	years)	 2017	 2016
Production machinery and equipment	5	\$ 575,091	\$ 810,996
Other machinery and equipment, primarily computers and			
research equipment	3 - 5	293,757	407,201
Furniture and fixtures	7	4,327	645,922
Purchased software	3	320,435	470,669
Leasehold improvements*	Term of Lease	 12,448	897,584
Total property and equipment		\$ 1,206,058	\$ 3,232,372

<sup>\*</sup> We amortize leasehold improvements over the term of the lease, which in all cases is shorter than the estimated useful life of the asset

No property or equipment was under capital lease at December 31, 2017 and 2016. During 2017, 2016 and 2015, we recorded \$232,000, \$496,000 and \$562,000, respectively, of depreciation and amortization related to property and equipment. See Note 1(i).

Property and equipment, net of accumulated amortization, in the amount of \$70,973 as of December 31, 2016 has been reclassified to noncurrent assets associated with discontinued operations. See Note 3.

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

The warrants have certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value, with subsequent changes in fair value included in earnings. The fair value of the warrants was estimated to be \$63,000 at issuance and at December 31, 2017 and 2016. See Notes 1(m) and 4. In addition, the MT Preferred Stock was immediately available for conversion upon issuance and includes a beneficial conversion feature, resulting in a deemed dividend of \$46,000 related to the beneficial conversion feature. Finally, certain provisions of the Securities Purchase Agreement obligate the MT Investors to acquire the remaining MT Preferred Stock and related warrants for \$2.0 million at the option of MT. The estimated relative fair value of this put option was \$113,000 at issuance based on the Black-Scholes option pricing model and is classified within stockholders' equity.

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

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

In July 2016, MT's Board of Directors authorized modification of the original investments of \$300,000 by Platinum and \$200,000 by Dr. Goldberg to a convertible preferred stock with a 10% PIK coupon retroactive to the time the initial investments were made. The conversion price of the preferred will remain at the \$500 million initial market cap but a full ratchet was added to enable the adjustment of conversion price, warrant number and exercise price based on the valuation of the first institutional investment round. In addition, the MT Board authorized issuance of additional convertible preferred stock with the same terms to Platinum as compensation for the additional \$200,000 of investments made in December 2015 and May 2016. Based on the MT Board's authorization of additional equity, the Company reclassified the additional \$200,000 from a current liability to equity during the year ended December 31, 2017. 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.

## 11. Investment in R-NAV, LLC

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

Both Rheumco and Navidea contributed licenses for intellectual property and technology to R-NAV in exchange for common units in R-NAV. The contributions of these licenses were recorded using the carryover basis. R-NAV was initially capitalized through a \$4.0 million investment from third-party private investors, and the technology contributions from Rheumco and Navidea. Navidea committed an additional \$1.0 million investment to be paid over three years, with \$333,334 in cash contributed at inception and a promissory note in the principal amount of \$666,666, payable in two equal installments on the first and second anniversaries of the transaction. A principal payment of \$333,333 was made on the note payable to R-NAV in July 2015. See Note 13. In exchange for its capital and in-kind investment, the Company received 3,500,000 Common Units and 1,000,000 Series A preferred units of R-NAV ("Series A Units"). The Company was to receive an additional 500,000 Series A Units for management and technical services associated with the programs described above performed by the Company for R-NAV pursuant to a services agreement.

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

Effective May 31, 2016, Navidea terminated its joint venture with R-NAV. Under the terms of the agreement, Navidea (1) transferred all of its shares of R-NAV, consisting of 1,500,000 Series A Preferred Units and 3,500,000 Common Units, to R-NAV; and (2) paid \$110,000 in cash to R-NAV. In exchange, R-NAV (1) transferred all of its shares of TcRA to Navidea, thereby returning the technology licensed to TcRA to Navidea; and (2) forgave the \$333,333 remaining on the promissory note. See Note 13. Neither Navidea nor R-NAV has any further obligations of any kind to either party. As a result of this transaction, the Company recognized a loss on disposal of the investment in R-NAV of \$39,732 during 2016.

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

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

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

## 12. Accounts Payable, Accrued Liabilities and Other

Accounts payable at December 31, 2017 and 2016 includes an aggregate of \$0 and \$116,000, respectively, due to related parties for director fees and MT scientific advisory board fees.

Accrued liabilities and other, including an aggregate of \$52,000 and \$106,000 due to related parties for director fees and MT scientific advisory board fees, at December 31, 2017 and 2016, respectively, consist of the following:

	2017	2016		
Contracted services	\$ 923,115	\$ 1,194,678		
Compensation	915,672	624,345		
Interest	_	5,756,519		
Other	19,061	297,351		
Total accrued liabilities and other	\$ 1,857,848	\$ 7,872,893		

Accounts payable in the amount of \$1,957,938 as of December 31, 2016 have been reclassified to current liabilities associated with discontinued operations. Accrued liabilities in the amount of \$7,092 and \$607,659 as of December 31, 2017 and 2016, respectively, have also been reclassified to current liabilities associated with discontinued operations. See Note 3.

## 13. Notes Payable

## Platinum

In July 2012, we entered into an agreement with Platinum to provide us with a credit facility of up to \$50.0 million. Following the approval of Tc99m tilmanocept, Platinum was committed under the terms of the agreement to extend up to \$35.0 million in debt financing to the Company. The agreement also provided for Platinum to extend an additional \$15.0 million on terms to be negotiated. Through June 25, 2013, we drew a total of \$8.0 million under the original facility.

In June 2013, in connection with entering into a Loan Agreement with General Electric Capital Corporation ("GECC") and MidCap Financial SBIC, LP ("MidCap") (the "GECC/MidCap Loan Agreement"), the Company and Platinum entered into an Amendment to the Platinum Loan Agreement (the "First Platinum Amendment"). Concurrent with the execution of the First Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the "First Amended Platinum Note") to Platinum, which amended and restated the original promissory note issued to Platinum, in the principal amount of up to \$35.0 million. The First Amended Platinum Note also adjusted the interest rate to the greater of (a) the U.S. Prime Rate as reported in the Wall Street Journal plus 6.75%; (b) 10%; or (c) the highest rate of interest then payable pursuant to the GECC/MidCap Loan Agreement plus 0.125%. In addition, the First Platinum Amendment granted Platinum the right, at Platinum's option subject to certain conditions, to convert all or any portion of the unpaid principal or unpaid interest accrued on any future draw (the "Conversion Amount"), beginning on a date two years from the date the draw is advanced, into the number of shares of Navidea's common stock computed by dividing the Conversion Amount by a conversion price equal to the lesser of (i) 90% of the lowest VWAP for the 10 trading days preceding the date of such conversion request, or (ii) the average VWAP for the 10 trading days preceding the date of such conversion request. The First Platinum Amendment also provided a conversion right on the same terms with respect to the amount of any mandatory repayment due following the Company achieving \$2.0 million in cumulative revenues from sales or licensing of Tc99m tilmanocept. Platinum's option to convert future draws into common stock was determined to meet the definition of a liability. The estimated fair value of the embedded conversion option is included in the carrying value of the new debt.

Also in connection with the First Platinum Amendment, the Company and Platinum entered into a Warrant Exercise Agreement ("Exercise Agreement"), pursuant to which Platinum exercised its Series X Warrant and Series AA Warrant. The warrants were exercised on a cashless basis by canceling a portion of the indebtedness outstanding under the Platinum Loan Agreement equal to \$4.8 million, the aggregate exercise price of the warrants. Pursuant to the Exercise Agreement, in lieu of common stock, Platinum received on exercise of the warrants 2,364.9 shares of the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock"), convertible into 7,733,223 shares of our common stock in the aggregate (3,270 shares of common stock per preferred share).

In March 2014, in connection with entering into the Oxford Loan Agreement (discussed below), we repaid all amounts outstanding under the GECC/MidCap Loan Agreement and entered into a second amendment to the Platinum Loan Agreement (the "Second Platinum Amendment"). Concurrent with the execution of the Second Platinum Amendment, the Company delivered an Amended and Restated Promissory Note (the "Second Amended Platinum Note") to Platinum, which amended and restated the First Amended Platinum Note. The Second Amended Platinum Note adjusted the interest rate to the greater of (i) the U.S. prime rate as reported in The Wall Street Journal plus 6.75%, (ii) 10.0%, and (iii) the highest rate of interest then payable by the Company pursuant to the Oxford Loan Agreement plus 0.125%.

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

The Platinum Note is reflected on the consolidated balance sheets at its principal balance plus the estimated fair value of the embedded conversion option of \$0 and \$153,000 at December 31, 2017 and 2016, respectively. During the years ended December 31, 2017, 2016 and 2015, changes in the estimated fair value of the Platinum conversion option were a decrease of \$153,000, a decrease of \$2.9 million and an increase of \$615,000, respectively, and were recorded as non-cash changes in the fair value of financial instruments. The balance of the Platinum Note, including the fair value of the embedded conversion option, was \$2.0 million and \$9.6 million as of December 31, 2017 and 2016, respectively.

The Platinum Loan Agreement, as amended, provided us with a credit facility of up to \$50 million. We drew a total of \$4.5 million and \$4.0 million under the credit facility in each of the years ended December 31, 2015 and 2013. We did not make any draws under the credit facility during the years ended December 31, 2016 and 2014. In addition, \$265,000, \$1.0 million and \$761,000 of interest was compounded and added to the balance of the Platinum Note during the years ended December 31, 2017, 2016 and 2015, respectively. In accordance with the terms of a Section 16(b) Settlement Agreement, Platinum agreed to forgive interest owed on the credit facility in an amount equal to 6%, effective July 1, 2016.

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. The Company was informed by PPVA that it was the owner of additional amounts owed on the Platinum-Montaur loan. PPVA claims a balance of approximately \$1.9 million was due upon closing of the Asset Sale. That amount is also subject to competing claims of ownership by Dr. Michael Goldberg, the Company's President and Chief Executive Officer. The Company has not yet paid the balance to anyone, as ownership is subject to dispute.

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of \$1,914,827.22 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement. Said action was removed to the United States District of New York on December 6, 2017. An initial pretrial conference was held on January 26, 2018. At the conference the Court stayed the deadline for the Company to answer or otherwise respond to the complaint. The Court also directed the parties to engage in informal jurisdictional discovery and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss is due on April 6, 2018. The Court also referred the case to a settlement conference, which has been scheduled for April 30, 2018. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

## Capital Royalty Partners II, L.P.

In May 2015, Navidea and MT, as guarantor, executed a Term Loan Agreement (the "CRG Loan Agreement") with Capital Royalty Partners II L.P. ("CRG") in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the "Lenders") in which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of \$50.0 million (the "CRG Term Loan"), with an additional \$10.0 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. Closing and funding of the CRG Term Loan occurred on May 15, 2015 (the "Effective Date"). The principal balance of the CRG Term Loan bore interest from the Effective Date at a per annum rate of interest equal to 14.0%. Through March 31, 2019, the Company had the option of paying (i) 10.00% of the per annum interest in cash and (ii) 4.00% of the per annum interest as compounded interest which is added to the aggregate principal amount of the CRG Term Loan. During 2016 and 2015, \$553,000 and \$1.3 million of interest was compounded and added to the balance of the CRG Term Loan. In addition, the Company began paying the cash portion of the interest in arrears on June 30, 2015. Principal was due in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, was due and payable in full on March 31, 2021.

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

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

The CRG Term Loan was collateralized by a security interest in substantially all of the Company's assets. In addition, the CRG Loan Agreement required that the Company adhere to certain affirmative and negative covenants, including financial reporting requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the CRG Loan Agreement. The Lenders could accelerate the payment terms of the CRG Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the CRG Loan Agreement, the failure of the Company to adhere to the covenants set forth in the CRG Loan Agreement, and the insolvency of the Company. The covenants of the CRG Loan Agreement included a covenant that the Company shall have EBITDA of no less than \$5.0 million in each calendar year during the term or revenues from sales of Tc99m tilmanocept in each calendar year during the term of at least \$22.5 million in 2016, with the target minimum revenue increasing in each year thereafter until reaching \$45.0 million in 2020. However, if the Company were to fail to meet the applicable minimum EBITDA or revenue target in any calendar year, the CRG Loan Agreement provided the Company a cure right if it raised 2.5 times the EBITDA or revenue shortfall in equity or subordinated debt and deposited such funds in a separate blocked account. Additionally, the Company was required to maintain liquidity, defined as the balance of unencumbered cash and permitted cash equivalent investments, of at least \$5.0 million during the term of the CRG Term Loan. The events of default under the CRG Loan Agreement also included a failure of Platinum to perform its funding obligations under the Platinum Loan Agreement at any time as to which the Company had negative EBITDA for the most recent fiscal quarter, as a result either of Platinum's repudiation of its obligations under the Platinum Loan Agreement, or the occurrence of an insolvency event with respect to Platinum. An event of default would entitle CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas on 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 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59.0 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in the Texas Court to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47.0 million and no more than \$66.0 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 agreed to post a \$7.0 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG agreed to post a \$12.0 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59.0 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2.0 million being held in escrow pursuant to court order in the Ohio case and the \$3.0 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. On March 3, 2017, Cardinal Health 414 posted a \$7.0 million letter of credit, and on March 7, 2017, CRG posted a \$12.0 million letter of credit, each as required by the Global Settlement Agreement.

The trial was held in Texas in December 2017. The Texas Court ruled that the Company's total obligation to CRG is 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 owes 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. The Company believes that this \$4.1 million should be credited against the \$7.0 million; CRG disagrees. On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the Texas Court's oversight of not explaining how to apply the \$4.1 million payment, requesting that the judgment be modified to set the supersedeas amount at \$2.9 million so that the Company can stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. The Texas Court has scheduled a hearing on the issue for March 26, 2018, however it has not yet set the amount, and enforcement of the judgment is stayed until seven days after the Texas Court does so. We currently await further action by the Texas Court. If we are ultimately required to pay an additional \$7.0 million to CRG, such payment would have a significant adverse effect on our financial position and would likely force us to curtail our planned development activities. See Notes 2 and 16.

### Oxford Finance, LLC

In March 2014, we executed a Loan and Security Agreement (the "Oxford Loan Agreement") with Oxford Finance, LLC ("Oxford"), providing for a loan to the Company of \$30.0 million. Pursuant to the Oxford Loan Agreement, we issued Oxford: (1) Term Notes in the aggregate principal amount of \$30.0 million, bearing interest at 8.5% (the "Oxford Notes"), and (2) Series KK warrants to purchase an aggregate of 391,032 shares of our common stock at an exercise price of \$1.918 per share, expiring in March 2021 (the "Series KK Warrants"). The Company recorded a debt discount related to the issuance of the Series KK Warrants and other fees to the lenders totaling \$3.0 million. Debt issuance costs directly attributable to the Oxford Loan Agreement, totaling \$120,000, were recorded as an additional debt discount on the consolidated balance sheet on the closing date. The debt discounts were being amortized as non-cash interest expense using the effective interest method over the term of the Oxford Loan Agreement.

We began making monthly payments of interest only on April 1, 2014, and monthly payments of principal and interest beginning April 1, 2015. In May 2015, in connection with the consummation of the CRG Loan Agreement, the Company repaid all amounts outstanding under the Oxford Loan Agreement. The payoff amount of \$31.7 million included payments of \$289,000 as a pre-payment fee and \$2.4 million as an end-of-term final payment fee. The Series KK warrants remained outstanding as of December 31, 2017.

## R-NAV, LLC

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

Effective May 31, 2016, Navidea terminated its joint venture with R-NAV. Under the terms of the agreement, Navidea (1) transferred all of its shares of R-NAV, consisting of 1,500,000 Series A Units and 3,500,000 Common Units, to R-NAV; and (2) paid \$110,000 in cash to R-NAV. In exchange, R-NAV (1) transferred all of its shares of TcRA to Navidea, thereby returning the technology licensed to TcRA to Navidea; and (2) forgave the \$333,333 remaining on the promissory note. Neither Navidea nor R-NAV has any further obligations of any kind to either party. See Note 11.

#### IPFS Corporation

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

In November 2017, we prepaid \$396,000 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 4.0%. The note is payable in ten monthly installments of \$40,000, with the final payment due in August 2018. The note is included in notes payable, current in the December 31, 2017 consolidated balance sheet.

## Summary

During the years ended December 31, 2017, 2016 and 2015, we recorded interest expense of \$159,000, \$5,000 and \$1.3 million, respectively, related to our notes payable. Of those amounts, \$326,000 during the year ended December 31, 2015 was non-cash in nature related to amortization of the debt discounts and deferred financing costs related to our notes payable. An additional \$134,000 of this interest expense was compounded and added to the balance of our notes payable during the year ended December 31, 2017.

Interest expense in the amount of \$1,706,491, \$14,856,404 and \$5,603,820 during the years ended December 31, 2017, 2016 and 2015, respectively, has been reclassified to discontinued operations. See Note 3.

Annual principal maturities of our notes payable are \$2.4 million in 2018.

## 14. Terminated Lease Liability

Effective June 1, 2017, Navidea relocated its Dublin, Ohio headquarters from 5600 Blazer Parkway ("Blazer") to a smaller space at 4995 Bradenton Avenue. The Company concurrently executed a sublease arrangement ("Sublease") for the Blazer space because there is no early termination provision in the Blazer lease. The Blazer lease and the Sublease end simultaneously in October 2022.

In accordance with current accounting guidance, the Company initially recorded a total liability of \$1.0 million, which was equal to the fair value of the remaining payments due under the Blazer Lease, net of the fair value of the payments to be received by the Company under the Sublease, and including a finder's fee. The Company also recorded a loss on contract termination of \$399,000 and a loss on disposal of assets, primarily leasehold improvements and furniture and fixtures, related to the Blazer space of \$706,000. Both losses are included in selling, general and administrative expenses for the year ended December 31, 2017.

A summary of the changes in our terminated lease liability during the year ended December 31, 2017 is presented below:

	Terminated Lease Liability
Total liability, June 1, 2017 (date of sublease)	\$ 943,675
Additional finder's fees required by contract	80,371
Changes in estimated future payments	(29,917)
Payment of finder's fees	(188,187)
Payments under Blazer lease	(329,880)
Receipts from subtenant	195,621
Accretion of liability	23,624
Total liability, December 31, 2017	\$ 695,307

#### 15. Leases

We currently lease approximately 5,000 square feet of office space at 4995 Bradenton Avenue, Dublin, Ohio, as our principal offices. The current least term expires in June 2020, at a monthly base rent of approximately \$3,000. We also lease approximately 2,000 square feet of office space at 560 Sylvan Avenue, Englewood Cliffs, New Jersey. The current lease term expires in March 2018, at a monthly base rent of approximately \$3,000.

In addition, we currently lease approximately 25,000 square feet of office space at 5600 Blazer Parkway, Dublin, Ohio, formerly our principal offices. The current lease term expires in October 2022, at a monthly base rent of approximately \$26,000 during 2018. 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.

As of December 31, 2017, the future minimum lease payments for the years ending December 31 are as follows:

	O	perating
		Leases
2018	\$	328,117
2019		326,533
2020		315,594
2021		304,201
2022		253,339
Thereafter		
Total future minimum lease payments	\$	1,527,784

Total rental expense was \$139,000, \$187,000 and \$217,000 for the years ended December 31, 2017, 2016 and 2015, respectively. See Note 1(1).

## 16. Commitments and Contingencies

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

Sinotau Litigation - NAV4694

On August 31, 2015, Sinotau filed a suit for damages, specific performance, and injunctive relief against the Company in the U.S. District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company's NAV4694 product candidate and technology. In September 2016, the Court denied the Company's motion to dismiss. The Company filed its answer to the complaint and the parties have filed multiple joint motions to stay the case pending settlement discussion, which to date have been granted. On October 26, 2017, the Company executed a letter of intent with Sinotau and Cerveau, outlining a plan to sublicense to Cerveau the worldwide rights to conduct research using NAV4694, as well as grant to Cerveau an exclusive license for the development, marketing and commercialization of NAV4694 in Australia, Canada, China and Singapore. The letter of intent includes a provision stating that Sinotau will release all claims in the Sinotau Litigation upon the parties' execution of a definitive agreement; the commercial rights agreement contemplated by the letter of intent would also include a release of such claims and a covenant not to sue on such claims.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas on 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 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59.0 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in the Texas Court to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47.0 million and no more than \$66.0 million. In addition, CRG agreed that Navidea had the right to assert all affirmative defenses to its claim of default. In the underlying case the district court had entered summary judgment in favor of CRG finding unspecified events of default but refusing to consider affirmative defenses raised by Navidea as not before the Court. Subsequent to the settlement CRG moved again for entry of judgment in its favor; Navidea objected that the Settlement Agreement specifically allowed it to raise affirmative defenses and the district court agreed with Navidea setting the case for trial in December 2017. CRG once again moved for summary judgment and the motion was heard by the Court on October 30, 2017.

Concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a \$7.0 million letter of credit in favor of CRG (at the Company's cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a \$12.0 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59.0 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2.0 million being held in escrow pursuant to court order in the Ohio case and the \$3.0 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale.

The trial was held in Texas in December 2017. The Texas Court ruled that the Company's total obligation to CRG is 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 owes 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. The Company believes that this \$4.1 million should be credited against the \$7.0 million; CRG disagrees. On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the Texas Court's oversight of not explaining how to apply the \$4.1 million payment, requesting that the judgment be modified to set the supersedeas amount at \$2.9 million so that the Company can stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. The Texas Court has scheduled a hearing on the issue for March 26, 2018, however it has not yet set the amount, and enforcement of the judgment is stayed until seven days after the Texas Court does so. We currently await further action by the Texas Court.

Navidea's management believes it is probable that the Company will be required to pay the \$2.9 million modified judgment requested in January 2018, and as such we accrued a loss contingency for that amount as a current liability on the December 31, 2017 consolidated balance sheet. The loss contingency of \$2.9 million was recorded as an additional loss on extinguishment of the CRG Term Loan on the consolidated statement of operations for the year ended December 31, 2017.

#### Former CEO Arbitration

On May 12, 2016 the Company received a demand for arbitration through the American Arbitration Association, Columbus, Ohio, from Ricardo J. Gonzalez, the Company's then Chief Executive Officer, claiming that he was terminated without cause and, alternatively, that he resigned in accordance with Section 4G of his Employment Agreement pursuant to a notice received by the Company on May 9, 2016. On May 13, 2016, the Company notified Mr. Gonzalez that his failure to undertake responsibilities assigned to him by the Board of Directors and otherwise work after being ordered to do so on multiple occasions constituted an effective resignation, and the Company accepted that resignation. The Company rejected the resignation of Mr. Gonzalez pursuant to certain provisions in Section 4G of his Employment Agreement. Also, the Company notified Mr. Gonzalez that, alternatively, his failure to return to work after the expiration of the cure period provided in his Employment Agreement constituted cause for his termination under his Employment Agreement. Mr. Gonzalez was seeking severance and other amounts claimed to be owed to him under his Employment Agreement. In response, the Company filed counterclaims against Mr. Gonzalez alleging malfeasance by Mr. Gonzalez in his role as Chief Executive Officer. Mr. Gonzalez withdrew his claim for additional severance pursuant to his Employment Agreement, and the Company withdrew its counterclaims. On May 12, 2017, the Company received a ruling in favor of Mr. Gonzalez finding that he was terminated by the Company without cause on April 7, 2016. Mr. Gonzalez was awarded salary, bonus, and benefits in the aggregate amount of \$481,039 plus interest, attorneys' fees, and other costs. The arbitration award is final and binding on the parties. The Company paid an aggregate of \$617,880 to Mr. Gonzalez on May 16, 2017.

#### FTI Consulting, Inc. Litigation

On October 11, 2016, FTI Consulting, Inc. ("FTI") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in excess of \$782,600 comprised of: (i) \$730,264 for investigative and consulting services FTI alleges to have provided to the Company pursuant to an Engagement Agreement between FTI and the Company, and (ii) in excess of \$52,337 for purported interest due on unpaid invoices, plus attorneys' fees, costs and expenses. On November 14, 2016, the Company filed an Answer and Counterclaim denying the allegations of the Complaint and seeking damages on its Counterclaim, in an amount to be determined at trial, for intentional overbilling by FTI. On February 7, 2017, a preliminary conference was held by the Court at which time a scheduling order governing discovery was issued. On June 26, 2017, the Company and FTI entered into a settlement agreement. According to FTI, as of June 2017, FTI was owed \$862,165 including interest charges and legal fees. Under the terms of the settlement agreement, the Company paid an aggregate of \$435,000 to FTI on June 30, 2017.

## Sinotau Litigation - Tc99m Tilmanocept

On February 1, 2017, Navidea filed suit against Sinotau in the U.S. District Court for the Southern District of Ohio. The Company's complaint included claims seeking a declaration of the rights and obligations of the parties to an agreement regarding rights for the Tc99m tilmanocept product in China and other claims. The complaint sought a temporary restraining order ("TRO") and preliminary injunction to prevent Sinotau from interfering with the Company's Asset Sale to Cardinal Health 414. On February 3, 2017, the Court granted the TRO and extended it until March 6, 2017. The Asset Sale closed on March 3, 2017. On March 6, the Court dissolved the TRO as moot. Sinotau also filed a suit against the Company and Cardinal Health 414 in the U.S. District Court for the District of Delaware on February 2, 2017. On July 12, 2017, the District of Delaware case was transferred to the Southern District of Ohio. On July 27, 2017 the Ohio Court determined that both cases in the Southern District of Ohio are related and the case was stayed for 60 days pending settlement discussions. On February 8, 2018, Navidea and Sinotau executed an amendment to the agreement, modifying certain terms of the agreement and effectively resolving the legal dispute. On February 17, 2018, Navidea and Sinotau executed a Settlement Agreement and Mutual Release, and on February 20, 2018, Navidea and Sinotau voluntarily dismissed their legal cases.

## Platinum-Montaur Life Sciences LLC

On November 2, 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in the amount of \$1,914,827.22 purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted are for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement (discussed above). Said action was removed to the United States District of New York on December 6, 2017. An initial pretrial conference was held on January 26, 2018. At the conference the Court stayed the deadline for the Company to answer or otherwise respond to the complaint. The Court also directed the parties to engage in informal jurisdictional discovery and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss is due on April 6, 2018. The Court also referred the case to a settlement conference, which has been scheduled for April 30, 2018. Because the funds sought by Platinum-Montaur are subject to claims of competing ownership, the Company intends to defend itself in the action and seek a determination as to whether any funds are due and owing to the plaintiff.

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, other than the CRG litigation for which we have accrued a contingent liability, will not materially affect our financial position.

#### 17. Preferred Stock

In August 2015, we entered into a Securities Exchange Agreement with two investment funds managed by Platinum to exchange 4,519 shares of Series B Preferred Stock held by Platinum for twenty-year warrants to purchase 14,777,130 shares of common stock of the Company at \$0.01 per share (the "Series LL warrants"). The Series B Preferred Stock was convertible into common stock at a conversion rate of 3,270 shares of common stock per share of Series B Preferred Stock resulting in an aggregate number of shares of common stock into which the Series B Preferred Stock was convertible of 14,777,130 shares. There was no other consideration paid or received for the exchange. No gain or loss was recognized in our consolidated financial statements as a result of the exchange. The exchange transaction was entered into in connection with the filing of an application to list the Company's common stock on the Tel Aviv Stock Exchange ("TASE") in order to comply with a listing requirement of the TASE that listed companies have only one class of equity securities issued and outstanding. Following the exchange, the Company has no shares of preferred stock outstanding.

## 18. Equity Instruments

**a. Stock Warrants:** At December 31, 2017, there are 16.9 million warrants outstanding to purchase our common stock. The warrants are exercisable at prices ranging from \$0.01 to \$3.04 per share with a weighted average exercise price per share of \$1.19.

The following table summarizes information about our outstanding warrants at December 31, 2017:

	Exercise Price	Number of Warrants	Expiration Date
Series BB	\$ 2.00	300,000	July 2018
Series HH	2.49	301,205	June 2023
Series II	3.04	275,000	June 2018
Series KK	1.918	391,032	March 2021
Series LL	0.01	4,365,280	August 2035
Series MM	2.50	150,000	September 2019
Series MM	2.50	150,000	October 2019
Series NN	 1.50	11,000,000	March 2022
Total warrants	\$ 1.19 *	16,932,517	

<sup>\*</sup> Weighted average exercise price.

In addition, at December 31, 2017, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at \$2,000 per share.

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

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

In October 2015, 5,000,000 Series LL warrants were exercised on a cashless basis in exchange for the issuance of 4,977,679 shares of our common stock. In January 2017, 5,411,850 Series LL warrants were exercised in exchange for the issuance of 5,411.850 shares of our common stock, resulting in gross proceeds to the Company of \$54,119.

In March 2017, in connection with the Asset Sale, the Company granted to each of Cardinal Health 414 and UCSD, a five-year Series NN warrant to purchase up to 10 million shares and 1 million shares, respectively, of the Company's common stock at an exercise price of \$1.50 per share, each of which warrant is subject to anti-dilution and other customary terms and conditions.

c. Common Stock Reserved: As of December 31, 2017, we have reserved 20,620,196 shares of authorized common stock for the exercise of all outstanding stock options and warrants.

#### 19. Reductions in Force

In March 2015, the Company initiated a reduction in force that included seven staff members and three executives. The executives continued as employees during transition periods of varying lengths, depending upon the nature and extent of responsibilities transitioned or wound down. During the year ended December 31, 2015, the Company recognized approximately \$1.3 million of net expense as a result of the reduction in force, which included actual and estimated separation costs as well as the impact of accelerated vesting or forfeiture of certain equity awards resulting from the separation of \$273,000.

There are no accrued separation costs remaining as of December 31, 2017 or 2016.

#### 20. Income Taxes

As of December 31, 2017 and 2016, our deferred tax assets ("DTAs") were approximately \$39.7 million and \$79.1 million, respectively. The components of our deferred tax assets are summarized as follows:

	As of December 31,				
		2017	2016		
Deferred tax assets:					
Net operating loss carryforwards	\$	29,570,581 \$	66,150,646		
R&D credit carryforwards		10,043,714	9,729,673		
AMT credit carryforward		1,229,979	_		
Stock compensation		576,024	1,368,458		
Intangibles		591,651	1,720,761		
Gain/loss from discontinued operations		(2,510,699)	_		
Temporary differences		207,447	132,476		
Deferred tax assets before valuation allowance		39,708,697	79,102,014		
Valuation allowance		(38,478,718)	(79,102,014)		
Net deferred tax assets	\$	1,229,979 \$	_		

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, 2017 and 2016 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), projected future taxable income, and tax-planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the 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, 2017 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 reduces the U.S. federal corporate tax rate from 35% to 21%, effective January 1, 2018. Consequently, we have 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, 2017. The impact of many provisions of the Tax Act lack clarity and is subject to interpretation until additional IRS guidance is issued. The ultimate impact of the Tax Act may differ from the Company's estimates due to changes in the interpretations and assumptions made as well as any forthcoming regulatory guidance.

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 percent 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 \$1.2 million in other noncurrent assets in the consolidated balance sheet as of December 31, 2017.

As of December 31, 2017 and 2016, we had U.S. net operating loss carryforwards of approximately \$131.8 million and \$193.3 million, respectively. Of those amounts, \$15.3 million relates to stock-based compensation tax deductions in excess of book compensation expense ("APIC NOLs") as of December 31, 2016, 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 as such eliminated all APIC NOLs with a full offset to a valuation allowance.

As of December 31, 2017 and 2016, we also had state net operating loss carryforwards of approximately \$20.4 million and \$28.2 million, respectively. The state net operating loss carryforwards will begin expiring in 2032.

At December 31, 2017 and 2016, we had U.S. R&D credit carryforwards of approximately \$9.7 million and \$9.4 million, respectively.

There were no expirations of U.S. net operating loss carryforwards or R&D credit carryforwards during 2017 or 2016. 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, 2017		
		U.S. Net Operating Loss	U.S. R&D Credit	
Generated	Expiration	Carryforwards	Carryforwards	
1998	2018	\$ —	\$ 1,173,387	
1999	2019	_	130,359	
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	19,577,479	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	
Total carryforwards		\$ 131,771,930	\$ 9,654,826	

During the years ended December 31, 2017, 2016 and 2015, Cardiosonix recorded losses for financial reporting purposes of \$5,000, \$13,000 and \$11,000, respectively. As of December 31, 2016, Cardiosonix had tax loss carryforwards in Israel of approximately \$7.7 million. Under Israeli tax law, net operating loss carryforwards do not expire. Due to the uncertainty surrounding the realization of the related deferred tax assets in future tax returns and the Company's intent to dissolve Cardiosonix in the near term, all of the deferred tax assets were fully offset by a valuation allowance at December 31, 2016. Cardiosonix was legally dissolved in September 2017 and as such we eliminated all tax loss carryforwards with a full offset to a valuation allowance.

Under Sections 382 and 383 of the IRC of 1986, as amended, the utilization of U.S. net operating loss and R&D tax credit carryforwards may be limited under the change in stock ownership rules of the IRC. The Company 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:

			Years Ended Dec	ember 31,		
	2017		2016		2015	
	Amount	%	Amount	%	Amount	%
Benefit at statutory rate	\$ (6,048,423)	(34.0)% 5	\$ (2,508,264)	(34.0)% \$	(7,835,163)	(34.0)%
Adjustments to valuation						
allowance	(26,080,051)	(146.6)%	2,354,656	31.9%	8,212,163	35.7%
Adjustments to R&D						
credit carryforwards	(291,745)	(1.6)%	(239,049)	(3.2)%	(612,087)	(2.7)%
Disqualified debt interest	_	0.0%	188,060	2.5%	438,007	1.9%
Tax law changes	28,731,045	161.5%	_	0.0%	_	0.0%
Permanent items and						
other	(373,315)	(2.2)%	204,597	2.8%	(202,920)	(0.9)%
Provision per financial						
statements	\$ (4,062,489)		<u> </u>	\$		

See Note 1(p).

## 21. 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, our R-NAV joint venture (terminated on May 31, 2016), NAV4694 and NAV5001 (license terminated in April 2015), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by Macrophage Therapeutics, Inc.

The information in the following tables is derived directly from each reportable segment's financial reporting. Certain revenue and expense amounts in the years ended December 31, 2017, 2016 and 2015 have been reclassified to discontinued operations. See Note 3.

Year Ended December 31, 2017	Diagnostics	<b>Therapeutics</b>	Corporate	Total
Tc99m tilmanocept sales revenue:				
United States	\$ —	\$ —	\$ —	\$ —
International	_	_	_	_
Tc99m tilmanocept license revenue	100,000	_	_	100,000
Tc99m tilmanocept royalty revenue	9,126	_	_	9,126
Grant and other revenue	1,506,232	195,079		1,701,311
Total revenue	1,615,358	195,079		1,810,437
Cost of goods sold	3,651	_	_	3,651
Research and development expenses, excluding depreciation				
and amortization	3,784,255	729,587	_	4,513,842
Selling, general and administrative expenses, excluding				
depreciation and amortization (a)	_	34,484	10,895,301	10,929,785
Depreciation and amortization (b)			240,166	240,166
Loss from operations (c)	(2,172,548)	(568,992)	(11,135,467)	(13,877,007)
Other income (expense) (d)	_	_	(3,912,679)	(3,912,679)
Benefit from income taxes	496,127	129,936	3,436,426	4,062,489
Loss from continuing operations	(1,676,421)	(439,056)	(11,611,720)	(13,727,197)
Income from discontinued operations, net of tax effect	88,673,053	_	_	88,673,053
Net income (loss)	86,996,632	(439,056)	(11,611,720)	74,945,856
Total assets, net of depreciation and amortization:				
United States	\$ 13,065,871	\$ 49,001	\$ 7,634,237	\$ 20,749,109
International	30,476	_	1,851	32,327
Capital expenditures	_	_	33,690	33,690

Year Ended December 31, 2016	D	iagnostics	Th	erapeutics	Corp	orate	_	Total
Tc99m tilmanocept sales revenue:	ø		¢.		¢.		Φ	
United States	\$	20.601	\$		\$	_	\$	20.601
International Tc99m tilmanocept license revenue		39,601 1,795,625		_		_		39,601 1,795,625
Grant and other revenue		3,011,642		124,766				3,136,408
						<u> </u>	_	4,971,634
Total revenue	_	4,846,868 62,260		124,766			_	
Cost of goods sold, excluding depreciation and amortization Research and development expenses, excluding depreciation		02,200		_		_		62,260
and amortization		6,375,929		762,151				7,138,080
Selling, general and administrative expenses, excluding		0,373,929		702,131		_		7,136,060
				62 150	7.	02 220		7 466 497
depreciation and amortization (a)		56.215		63,158		03,329		7,466,487
Depreciation and amortization (b)		56,317				97,232	_	453,549
Loss from operations (c)		(1,647,638)		(700,543)	(7,8	300,561)	(	(10,148,742)
Other income (expense), excluding equity in the loss of R-NAV, LLC <sup>(d)</sup>		_		_	2,7	86,007		2,786,007
Equity in the loss of R-NAV, LLC		_		_		(15,159)		(15,159)
Loss from continuing operations		(1,647,638)		(700,543)	_	29,713)		(7,377,894)
Loss from discontinued operations, net of tax effect		(6,931,137)			,			(6,931,137)
Net loss	-	(8,578,775)		(700,543)	(5,0	29,713)		(14,309,031)
Total assets, net of depreciation and amortization:				, , ,	,	, ,		, , ,
United States	\$	3,815,271	\$	15,075	\$ 8,4	98,797	\$	12,329,143
International		131,752		_		781		132,533
Capital expenditures		_		_		1,847		1,847
Year Ended December 31, 2015	D	iagnostics	Th	erapeutics	Corn	orate		Total
Tc99m tilmanocept sales revenue:		lagilostics	111	crapeuties	Corp	oracc	-	Total
United States	\$		\$	_	\$		\$	_
International	Ψ	19,075	Ψ	_	Ψ		Ψ	19,075
Tc99m tilmanocept license revenue		1,133,333		_		_		1,133,333
Grant and other revenue		1,860,953		_				1,860,953
Total revenue	_	3,013,361			1		_	3,013,361
Cost of goods sold, excluding depreciation and amortization	_	3,226		_				3,226
Research and development expenses, excluding depreciation		2,220						5,220
and amortization		9,831,834		730,895		_		10,562,729
Selling, general and administrative expenses, excluding		,,001,00		, 20,032				10,002,729
depreciation and amortization (a)		_		123,884	10.2	42,066		10,365,950
Depreciation and amortization (b)		232,091		123,001		290,105		522,196
	_		_	(0.5.4.550)			_	
Loss from operations (c)		(7,053,790)		(854,779)	(10,5	32,171)		(18,440,740)
Other income (expense), excluding equity in the loss of R-					(4.0	00 (04)		(4.200.604)
NAV, LLC <sup>(d)</sup>					` '	98,604)		(4,298,604)
Equity in the loss of R-NAV, LLC						05,253)		(305,253)
Loss from continuing operations		(7,053,790)		(854,779)	(15,1	36,028)	(	(23,044,597)
Income (loss) from discontinued operations, net of tax effect		/ <b></b> 46 -65				0.1.650		/
(e)		(5,713,598)				94,660		(4,518,938)
Net loss	(	(12,767,388)		(854,779)	(13,9	41,368)		(27,563,535)
Total assets, net of depreciation and amortization:	<b>C</b>	4 1 6 1 0 2 0	¢.		Φ 10.2	01.005	ф	14.550.001
United States	\$	4,161,029	\$	_	\$ 10,3	91,805	\$	14,552,834
International		410,666				1,013		411,679
Capital expenditures		26,589		_		12,412		39,001
I	F-37							

- (a) General and administrative expenses, excluding depreciation and amortization, represent costs that relate to the general administration of the Company and as such are not currently allocated to our individual reportable segments. Marketing and selling expenses are allocated to our individual reportable segments.
- (b) Depreciation and amortization is reflected in research and development (\$0, \$0 and \$10,617 for the years ended December 31, 2017, 2016 and 2015, respectively), and selling, general and administrative expenses (\$240,166, \$397,232 and \$460,839 for the years ended December 31, 2017, 2016 and 2015, respectively).
- (c) Loss from operations does not reflect the allocation of certain selling, general and administrative expenses, excluding depreciation and amortization, to our individual reportable segments.
- (d) Amounts consist primarily of interest income, interest expense, changes in fair value of financial instruments, and losses on debt extinguishment, which are not currently allocated to our individual reportable segments.
- (e) Amount not allocated to a reportable segment represents contingent consideration recognized related to 2015 GDS Business revenue royalties pursuant to the 2011 sale of the GDS Business to Devicor, net of tax effect. See Note 1(a).

## 22. Agreements

a. Supply Agreements: In November 2009, we entered into a manufacture and supply agreement with Reliable Biopharmaceutical Corporation ("Reliable") for the manufacture and supply of the Tc99m tilmanocept drug substance. The initial ten-year term of the agreement expires in November 2019, with options to extend the agreement for successive three-year terms. Either party had the right to terminate the agreement upon mutual written agreement, or upon material breach by the other party if not cured within 60 days from the date of written notice of the breach. Total purchases under the manufacture and supply agreement were \$0, \$1.1 million and \$225,000 for the years ended December 31, 2017, 2016 and 2015, respectively. Upon closing of the Asset Sale to Cardinal Health 414, our contract and open purchase order with Reliable were transferred to Cardinal Health 414.

In May 2013, we entered into a clinical supply agreement with Nordion (Canada), Inc. ("Nordion") for the manufacture and supply of NAV5001 clinical trial material. The initial three-year term expired in May 2016. In August 2014, in connection with the Company's decision to refocus its resources, the Nordion agreement was amended to provide for a suspension period during which the Company was to pay a monthly fee to maintain production space at Nordion's facility until such time as manufacture resumed. The Nordion agreement was terminated in March 2016. Total purchases under the clinical supply agreement were \$0, \$43,000 and \$244,000 for the years ended December 31, 2017, 2016 and 2015, respectively.

In August 2013, we entered into a manufacturing services agreement with PETNET Solutions, Inc. ("PETNET") for the manufacture and distribution of NAV4694. The initial three-year term of the agreement expired in August 2016 and the agreement was not renewed. Total purchases under the manufacturing agreement were \$0, \$826,000 and \$855,000 for the years ended December 31, 2017, 2016 and 2015, respectively.

In September 2013, we entered into a manufacturing services agreement with OSO BioPharmaceuticals Manufacturing, LLC ("OsoBio") for contract pharmaceutical development, manufacturing, packaging and analytical services for Tc99m tilmanocept. Either party had the right to terminate the agreement upon mutual written agreement, or upon material breach by the other party if not cured within 60 days from the date of written notice of the breach. During the term of agreement, OsoBio was the primary supplier of manufacturing services for Tc99m tilmanocept. In consideration for these services, the Company paid a unit pricing fee. In addition, the Company also paid OsoBio a fee for regulatory and other support services. Total purchases under the manufacturing services agreement were \$250,000, \$1.2 million and \$472,000 for the years ended December 31, 2017, 2016 and 2015, respectively. Upon closing of the Asset Sale to Cardinal Health 414, our contract and open purchase orders with OsoBio were transferred to Cardinal Health 414.

Also in September 2013, we completed a service and supply master agreement with Gipharma S.r.l. ("Gipharma") for process development, manufacturing and packaging of reduced-mass vials to be sold in the EU. The agreement had an initial term of three years and automatically renewed for an additional one-year periods. In consideration for these services, the Company paid fees as defined in the agreement. Total purchases under the service and supply master agreement were \$14,000, \$149,000 and \$677,000 for the years ended December 31, 2017, 2016 and 2015, respectively. Following the transfer of the Tc99m tilmanocept Marketing Authorization to SpePharm, our contract with Gipharma was transferred to SpePharm.

b. Research and Development Agreements In January 2002, we completed a license agreement with 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. Total costs related to the UCSD license agreement for net sales and royalties of Tc99m tilmanocept outside the Territory were \$4,000, \$2,000 and \$1,000 in 2017, 2016 and 2015, respectively. Royalties on net sales of Tc99m tilmanocept outside the Territory were recorded in cost of goods sold.

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 the Product in the Territory. Pursuant to the Purchase Agreement, the Company granted to UCSD a five (5)-year warrant to purchase up to 1 million shares of the Company's common stock, par value \$.001 per share, at an exercise price of \$1.50 per share.

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). 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 \$253,000, \$199,000 and \$152,000 in 2017, 2016 and 2015, respectively, and were recorded in research and development expenses.

In December 2011, we executed a license agreement with AstraZeneca AB for NAV4694, a proprietary compound that is primarily intended for use in diagnosing Alzheimer's disease and other CNS disorders. The license agreement is effective until the later of the tenth anniversary of the first commercial sale of NAV4694 or the expiration of the underlying patents. Under the terms of the license agreement, AstraZeneca granted us an exclusive worldwide royalty-bearing license for NAV4694 with the right to grant sublicenses. In consideration for the license rights, we paid AstraZeneca a license issue fee of \$5.0 million upon execution of the agreement. We also agreed to pay AstraZeneca up to \$6.5 million in contingent milestone payments based on the achievement of certain clinical development and regulatory filing milestones, and up to \$11.0 million in contingent milestone payments due following receipt of certain regulatory approvals and the initiation of commercial sales of the licensed product. In addition, we agreed to pay AstraZeneca a royalty on net sales of licensed and sublicensed products. Total costs (adjustments) related to the AstraZeneca license agreement were \$(70,000), \$116,000 and \$80,000 in 2017, 2016 and 2015, respectively, and were recorded in research and development expenses.

In July 2012, we entered into an agreement with Alseres to sublicense NAV5001, an Iodine-123 radiolabeled imaging agent being developed as an aid in the diagnosis of Parkinson's disease and other movement disorders, with a potential use as a diagnostic aid in dementia. Under the terms of the sublicense agreement, Alseres granted Navidea an exclusive, worldwide sublicense to research, develop and commercialize NAV5001. The terms of the agreement required Navidea to make a one-time sublicense execution payment to Alseres equal to (i) \$175,000 in cash and (ii) 300,000 shares of our common stock. The sublicense agreement also provided for contingent milestone payments of up to \$2.9 million, \$2.5 million of which would have principally occurred at the time of product registration or upon commercial sales, and the issuance of up to an additional 1.15 million shares of Navidea common stock, 950,000 shares of which would have been issuable at the time of product registration or upon commercial sales. In addition, the sublicense terms anticipated royalties on annual net sales of the approved product which were consistent with industry-standard terms and certain sublicense extension fees, payable in cash and shares of common stock, in the event certain diligence milestones were not met. In April 2015, the Company entered into an agreement with Alseres to terminate the Alseres sublicense agreement. Under the terms of this agreement, Navidea transferred all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres agreed to reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, Navidea has supplied clinical support services for NAV5001 on a cost-plus reimbursement basis. However, to this point, Alseres has been unsuccessful in raising the funds necessary to restart the program and reimburse Navidea. As a result, we have taken steps to end our obligations under the agreement and notified Alseres that we consider them in breach of the agreement. To date, we have not been successful in our efforts to recover the funds we expended complying with our obligations under the termination agreement. Total costs related to the Alseres sublicense agreement were \$0, \$0 and \$5,000 in 2017, 2016 and 2015, respectively, and were recorded in research and development expenses.

c. Employment Agreements: As of December 31, 2017, we had an employment agreement with one of our senior officers. In addition, although certain other employment agreements expired on or before December 31, 2017, the terms of the agreements provide for continuation of certain terms of the employment agreements as long as the senior officers continue to be employees of the Company following expiration of the agreements. The employment agreements contain termination and/or change in control provisions that would entitle each of the officers to 1.3 to 3.0 times their annual salaries, vest outstanding restricted stock and options to purchase common stock, and continue certain benefits if there is a termination without cause or change in control of the Company (as defined) and their employment terminates. As of December 31, 2017, our maximum contingent liability under these agreements in such an event is approximately \$2.5 million. The employment agreements generally also provide for severance, disability and death benefits.

## 23. 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 \$12,000, \$47,000 and \$73,000 during 2017, 2016 and 2015, respectively.

#### 24. Supplemental Disclosure for Statements of Cash Flows

During 2017, 2016 and 2015, we paid interest aggregating \$7.4 million, \$5.5 million and \$4.6 million, respectively. Interest paid during 2016 included collection fees of \$778,000 and a prepayment premium of \$2.1 million, both of which were withdrawn by CRG from a bank account under their control. During 2017, we issued 1 million Series NN warrants to UCSD with an estimated fair value of \$334,000. During 2017, 2016, and 2015, we issued 105,308, 67,002 and 68,157 shares of our common stock, respectively, as matching contributions to our 401(k) Plan which were valued at \$54,000, \$121,000 and \$117,000, respectively. In November 2017, we prepaid \$396,000 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 4.0%. In December 2016, we prepaid \$348,000 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 8.99%. During 2015, we recorded \$1.0 million of end-of-term fees associated with our notes payable to CRG.

As discussed in Note 10, the liability for the additional \$200,000 of investments made by Platinum was reclassified to additional paid-in-capital in January 2017. In connection with their initial investment in March 2015, the investors in MT were issued warrants that have been determined to be derivative liabilities with an estimated fair value of \$63,000. A \$46,000 deemed dividend related to the beneficial conversion feature within the MT Preferred Stock was also recorded at the time of the initial investment in MT.

## 25. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for fiscal 2017 and 2016 are presented in the following table, in thousands, except per share data. Certain revenue and expense amounts in the years ended December 31, 2017 and 2016 have been reclassified to discontinued operations. See Note 3.

	For the Quarter Ending							
	September							
	M	arch 31		June 30		30	De	cember 31
2017:								
Tc99m tilmanocept sales revenue	\$	_	\$	_	\$	_	\$	_
Tc99m tilmanocept license revenue				100		_		_
Tc99m tilmanocept royalty revenue		_		_		_		9
Grant and other revenue		580		512		224		386
Gross profit		580		612		224		391
Operating expenses		3,728		5,435		2,609		3,912
Loss from operations		(3,148)		(4,823)		(2,385)		(3,521)
Loss before income taxes		(4,319)		(4,783)		(2,317)		(6,371)
Benefit from (provision for) income taxes		1,454		1,631		776		201
Loss from continuing operations		(2,865)		(3,152)		(1,541)		(6,170)
Gain (loss) from discontinued operations, net of tax		88,446		(2,036)		151		2,112
Net income (loss) attributable to common stockholders		85,581		(5,188)		(1,390)		(4,058)
Loss per common share (basic) (1):								
Continuing operations	\$	(0.02)	\$	(0.02)	\$	(0.01)	\$	(0.04)
Discontinued operations	\$	0.55	\$	(0.01)			\$	0.01
Attributable to common stockholders	\$	0.53	\$	(0.03)		(0.01)	\$	(0.03)
Loss per common share (diluted) (1):								
Continuing operations	\$	(0.02)	\$	(0.02)	\$	(0.01)	\$	(0.04)
Discontinued operations	\$	0.54	\$	(0.01)	\$		\$	0.01
Attributable to common stockholders	\$	0.52	\$	(0.03)	\$	(0.01)	\$	(0.03)
2016:								
Tc99m tilmanocept sales revenue	\$	9	\$	4	\$	18	\$	9
Tc99m tilmanocept license revenue		254		246		1,296		_
Grant and other revenue		686		917		511		1,022
Gross profit		947		1,166		1,821		975
Operating expenses		4,705		3,407		2,731		4,215
Loss from operations		(3,758)		(2,241)		(910)		(3,240)
Loss from continuing operations		(2,682)		(817)		(1,761)		(2,118)
Gain (loss) from discontinued operations, net of tax		(1,004)		(5,865)		1,702		(1,764)
Net loss attributable to common stockholders		(3,686)		(6,682)		(59)		(3,882)
Loss per common share (basic and diluted) (1):								
Continuing operations	\$	(0.02)	\$	(0.01)		(0.01)	\$	(0.01)
Discontinued operations	\$	0.00	\$	(0.03)	\$	0.01	\$	(0.02)
Attributable to common stockholders	\$	(0.02)	\$	(0.04)	\$	(0.00)	\$	(0.03)

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

## 26. Subsequent Events:

- a. CRG Litigation and Settlement: On January 16, 2018, the Company filed an emergency motion to set supersedeas bond and to modify judgment, describing the Texas Court's oversight of not explaining how to apply the \$4.1 million payment, requesting that the judgment be modified to set the supersedeas amount at \$2.9 million so that the Company can stay enforcement of the judgment pending appeal. The Texas Court refused to rule on this motion, and the court of appeals entered an order compelling the Texas Court to set a supersedeas amount. The Texas Court has scheduled a hearing on the issue for March 26, 2018, however it has not yet set the amount, and enforcement of the judgment is stayed until seven days after the Texas Court does so. We currently await further action by the Texas Court. See Notes 13 and 16.
- b. Platinum Litigation: An initial pretrial conference was held on January 26, 2018. At the conference the Court stayed the deadline for the Company to answer or otherwise respond to the complaint. The Court also directed the parties to engage in informal jurisdictional discovery and a follow up status conference was held on March 9, 2018, during which the Court set a briefing schedule and determined that Navidea's motion to dismiss is due on April 6, 2018. The Court also referred the case to a settlement conference, which has been scheduled for April 30, 2018. See Notes 13 and 16.

## 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. 333-222092, 333-195806, 333-19330, 333-184173, 333-173752, 333-168485, 333-76151, and 333-15989) and Form S-8 (Nos. 33-81410, 333-119219, 333-130636, 333-130640, 333-153110, 333-158323, 333-183317, 333-05143, 333-21053, 333-05143, 333-198716, and 333-217814) of our report dated March 14, 2018, with respect to our audit of the consolidated financial statements of Navidea Biopharmaceuticals, Inc. as of December 31, 2017 and 2016 and for the years then ended and our report dated March 14, 2018 with respect to our audit of the effectiveness of internal control over financial reporting of Navidea Biopharmaceuticals, Inc. as of December 31, 2017, which reports are included in this Annual Report on Form 10-K of Navidea Biopharmaceuticals, Inc. for the year ended December 31, 2017.

/s/ Marcum LLP

New Haven, CT March 15, 2018

## Consent of Independent Registered Public Accounting Firm

Navidea Biopharmaceuticals, Inc. Dublin, Ohio

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-222092) and Form S-8 (No. 333-119219, 333-130636, 333-130640, 333-153110, 333-158323, 333-183317, 333-198716 and 333-217814) of Navidea Biopharmaceuticals, Inc. of our report dated March 23, 2016, relating to the consolidated financial statements of Navidea Biopharmaceuticals, Inc., which appears in this Form 10-K.

/s/ BDO USA, LLP

Chicago, Illinois March 15, 2018

#### **POWER OF ATTORNEY**

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

- To sign and file with the United States Securities and Exchange Commission the Annual Report of the Company on Form 10-K (the "Annual Report") for the fiscal year ended December 31, 2017, 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 15, 2018.

Signature	Title
C	President, Chief Executive Officer and Director
/s/ Michael M. Goldberg Michael M. Goldberg, M.D.	(principal executive officer)
Wilchael W. Goldberg, W.D.	(principal executive officer)
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Chief Operating Officer and Chief Financial Officer
/s/ Jed A. Latkin	_
Jed A. Latkin	(principal financial officer and principal accounting officer)
/s/ Eric K. Rowinsky	
Eric K. Rowinsky, M.D.	Chairman of the Board of Directors
Claudine Bruck, Ph.D.	Director
•	
/s/ Mark I. Greene	<u></u>
Mark I. Greene, M.D., Ph.D., FRCP	Director
/s/ Y. Michael Rice	
Y. Michael Rice	Director

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

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

March 15, 2018

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

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

#### I, Jed A. Latkin, certify that:

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

March 15, 2018

/s/ Jed A. Latkin

Jed A. Latkin

Chief Operating Officer and Chief Financial Officer

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

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

- (1) The periodic report containing financial statements to which this certificate is an exhibit fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the periodic report to which this certificate is an exhibit fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

March 15, 2018

/s/ Michael M. Goldberg

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

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

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

- (1) The periodic report containing financial statements to which this certificate is an exhibit fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the periodic report to which this certificate is an exhibit fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

March 15, 2018 /s/ Jed A. Latkin

Jed A. Latkin

Chief Operating Officer and Chief Financial Officer