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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

or

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

For the transition period from _____ to _____

Commission File Number: 001-35076

NAVIDEA BIOPHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**31-1080091**
State or Other Jurisdiction of Incorporation or Organization	IRS Employer Identification No.
4995 Bradenton Avenue, Suite 240, Dublin, Ohio	**43017-3552**
Address of Principal Executive Offices	Zip Code

(614) 793-7500
Registrant's Telephone Number, Including Area Code

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock	NAVB	NYSE American
Preferred Stock Purchase Rights	N/A	NYSE American

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging Growth Company	☐		

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 35,064,475 shares of common stock, par value $.001 per share (as of the close of business on May 9, 2023).

NAVIDEA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	March 31, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,795	$ 1,995,860
Receivables	31,043	630
Inventory, net	460,636	427,344
Prepaid expenses and other	672,060	780,110
Total current assets	1,197,534	3,203,944
Property and equipment	734,870	835,845
Less accumulated depreciation and amortization	598,449	700,498
Property and equipment, net	136,421	135,347
Right-of-use lease assets	107,243	107,243
Less accumulated amortization	95,938	86,943
Right-of-use lease assets, net	11,305	20,300
License agreements, patents and trademarks	1,239,477	1,215,604
Less accumulated amortization	228,925	215,363
License agreements, patents and trademarks, net	1,010,552	1,000,241
Other assets	11,774	11,774
Total assets	$ 2,367,586	$ 4,371,606

See accompanying notes to condensed consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets (continued)

	March 31, 2023 (unaudited)	December 31, 2022
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 3,171,126	$ 2,122,538
Accrued liabilities and other	4,925,845	6,456,762
Notes payable, current	343,074	543,613
Lease liabilities, current	10,372	18,976
Deferred revenue, current	800,000	800,000
Total current liabilities	9,250,417	9,941,889
Lease liabilities, net of current portion	926	1,312
Note payable to related party, net of discount	1,963,866	1,871,715
Deferred revenue	700,000	700,000
Total liabilities	11,915,209	12,514,916
Commitments and contingencies (See Note 10)		
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; 0 shares issued or outstanding as of March 31, 2023 and December 31, 2022	—	—
Series D preferred stock; $.001 par value, 150,000 shares authorized; 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Series E preferred stock; $.001 par value, 50,000 shares authorized; 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Series G preferred stock; $.001 par value, 3,260 shares authorized; 3,260 shares issued and outstanding as of March 31, 2023 and December 31, 2022	3	3
Series H preferred stock; $.001 par value, 75,000 shares authorized; 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Series I preferred stock; $.001 par value, 35,000 shares authorized; 9,480 shares issued and outstanding as of March 31, 2023 and December 31, 2022	10	10
Common stock; $.001 par value, 300,000,000 shares authorized; 32,851,252 and 32,687,666 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	223,848	223,684
Additional paid-in capital	379,414,977	379,343,124
Accumulated deficit	(389,478,978)	(388,002,649)
Total stockholders' deficit	(9,840,140)	(8,435,828)
Noncontrolling interest	292,517	292,518
Total Navidea stockholders' deficit	(9,547,623)	(8,143,310)
Total liabilities and stockholders' deficit	$ 2,367,586	$ 4,371,606

See accompanying notes to condensed consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	1,267,453	1,169,254
Selling, general and administrative	1,154,916	1,810,030
Total operating expenses	2,422,369	2,979,284
Loss from operations	(2,422,369)	(2,979,284)
Other income (expense):		
Interest expense, net	(263,195)	(3,662)
Gain on amendment of contracts	1,226,432	—
Other, net	(17,198)	(4,299)
Total other income (expense), net	946,039	(7,961)
Net loss	(1,476,330)	(2,987,245)
Loss attributable to noncontrolling interest	1	3
Loss attributable to common stockholders	$ (1,476,329)	$ (2,987,242)
Loss attributable to common stockholders per common share (basic and diluted)	$ (0.05)	$ (0.10)
Weighted average shares outstanding	32,654,012	30,207,746

See accompanying notes to condensed consolidated financial statements.

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

For the Three Months Ended March 31, 2023

	Preferred Stock		Common Stock Issued		Additional Paid-In Capital	Accumulated Deficit	Non-controlling Interest	Total
	Shares	Amount	Shares	Amount				
Balance, January 1, 2023	**12,740**	**$ 13**	**32,687,666**	**$ 223,684**	**$ 379,343,124**	**$ (388,002,649)**	**$ 292,518**	**$ (8,143,310)**
Issued stock to 401(k) plan	**-**	**-**	**163,586**	**164**	**52,184**	**-**	**-**	**52,348**
Stock compensation expense	**-**	**-**	**-**	**-**	19,669	**-**	**-**	19,669
Net loss	**-**	**-**	**-**	**-**	**-**	**(1,476,329)**	**(1)**	**(1,476,330)**
Balance, March 31, 2023	**12,740**	**$ 13**	**32,851,252**	**$ 223,848**	**$ 379,414,977**	**$ (389,478,978)**	**$ 292,517**	$ (9,547,623)

For the Three Months Ended March 31, 2022

	Preferred Stock		Common Stock Issued		Additional Paid-In Capital	Accumulated Deficit	Non-controlling Interest	Total
	Shares	Amount	Shares	Amount				
Balance, January 1, 2022	72,077	**$ 72**	30,279,922	**$ 221,277**	**$ 370,459,705**	**$ (370,787,610)**	**$ 731,299**	**$ 624,743**
Issued stock in lieu of cash bonuses	-	-	16,632	17	16,948	-	-	16,965
Issued stock to 401(k) plan	-	-	53,238	53	44,667	-	-	44,720
Issued stock in lieu of cash for payment of director fees	-	-	7,500	7	6,518	-	-	6,525
MT Preferred Stock reacquired due to Platinum settlement	**-**	-	**-**	-	438,778	-	(438,778)	-
Stock compensation expense	**-**	-	**-**	-	184,850	-	-	184,850
Net loss	**-**	-	**-**	-	-	(2,987,242)	(3)	(2,987,245)
Balance, March 31, 2022	72,077	**$ 72**	30,357,292	**$ 221,354**	**$ 371,151,466**	**$ (373,774,852)**	**$ 292,518**	**$ (2,109,442)**

See accompanying notes to condensed consolidated financial statements.

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (1,476,330)	$ (2,987,245)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	27,555	22,878
Non-cash lease expense	8,995	30,354
Loss on abandonment of patent applications	469	47,774
Stock compensation expense	19,669	184,850
Value of stock issued to 401(k) plan for employer matching contributions	52,348	44,720
Value of stock issued in payment of employee bonuses	—	16,965
Value of stock issued in payment of director fees	—	6,525
Gain on amendment of contracts	(1,226,432)	—
Amortization of debt discount and issuance costs	92,151	—
Changes in operating assets and liabilities:		
Receivables	(30,413)	(22,852)
Inventory	(33,292)	(171,837)
Prepaid expenses and other assets	108,050	240,832
Accounts payable	1,048,588	143,616
Accrued and other liabilities	(304,485)	(149,083)
Lease liabilities	(8,990)	(86,567)
Deferred revenue	—	122,964
Net cash used in operating activities	(1,722,117)	(2,556,106)
Cash flows from investing activities:		
Payments for purchases of equipment	(15,068)	(42,017)
Patent and trademark costs	(24,341)	(76,175)
Net cash used in investing activities	(39,409)	(118,192)
Cash flows from financing activities:		
Principal payments on notes payable	(200,539)	(339,453)
Net cash used in financing activities	(200,539)	(339,453)
Net decrease in cash and cash equivalents	(1,962,065)	(3,013,751)
Cash and cash equivalents, beginning of period	1,995,860	4,230,865
Cash and cash equivalents, end of period	$ 33,795	$ 1,217,114

See accompanying notes to condensed consolidated financial statements.

Notes to the Condensed Consolidated Financial Statements (unaudited)

1. Summary of Significant Accounting Policies

a. Basis of Presentation: The information presented as of March 31, 2023 and for the three-month periods ended March 31, 2023 and 2022 is unaudited, but includes all adjustments (which consist only of normal recurring adjustments) that the management of Navidea Biopharmaceuticals, Inc. ("Navidea", the "Company," or "we") believes to be necessary for the fair presentation of results for the periods presented. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. The balances as of March 31, 2023 and the results for the interim periods are not necessarily indicative of results to be expected for the year. The condensed consolidated financial statements should be read in conjunction with Navidea's audited consolidated financial statements for the year ended December 31, 2022, which were included as part of our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 27, 2023 ("2022 Form 10-K").

Our condensed consolidated financial statements include the accounts of Navidea and our wholly owned subsidiaries, Navidea Biopharmaceuticals Europe Limited ("Navidea Europe") and Navidea Biopharmaceuticals Limited ("Navidea UK"), as well as those of our majority-owned subsidiary, Macrophage Therapeutics, Inc. ("MT"). All significant inter-company accounts were eliminated in consolidation.

b. 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.

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

We also earn revenue from product sales to end customers, primarily in Europe. Revenue from product sales is generally recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which occurs upon either shipment of the product or arrival at its destination, depending upon the shipping terms of the transaction. 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.

In addition, we 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 ("R&D") costs, milestone payments, and royalties. Each licensing and distribution agreement is unique and requires separate assessment in accordance with current accounting standards. See Note 3.

d. Net Loss Per Share: Net loss per share is calculated in accordance with the two-class method. Under the two-class method, net loss is allocated between common stock and other participating securities based on their participation rights. We have determined that the outstanding nonvested restricted stock represents participating securities. Net losses are not allocated to the nonvested restricted stockholders for calculating net loss per share under the two-class method because nonvested restricted stockholders do not have contractual obligations to share in the losses of the Company. Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, excluding the effects of any potentially dilutive instruments. Diluted net loss per share is calculated using the more dilutive of (a) the two-class method, or (b) treasury stock method, as applicable, to the potentially dilutive instruments. The weighted average number of shares of common stock outstanding during the period reflects additional common shares that would have been outstanding if dilutive potential shares of common stock had been issued. Potential shares of common stock that may be issued by the Company include convertible preferred stock, options and warrants. See Note 5.

e. Research and Development Costs: 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.

f. 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 6.

g. **Intangible Assets:** Intangible assets consist primarily of license agreements, and patent and trademark costs. Intangible assets are stated at cost, less accumulated amortization. License agreements and patent costs are amortized using the straight-line method over the estimated useful lives of the license agreements and patents of approximately 5 to 15 years. Patent application costs are deferred pending the outcome of patent applications. Costs associated with unsuccessful patent applications and abandoned intellectual property are expensed when determined to have no recoverable value. We evaluate the potential alternative uses of all intangible assets, as well as the recoverability of the carrying values of intangible assets, on a recurring basis. During the three-month periods ended March 31, 2023 and 2022, we capitalized patent and trademark costs of $24,341 and $76,175, respectively. During the three-month periods ended March 31, 2023 and 2022, we abandoned patent applications with previously-capitalized patent costs of $469 and $47,774, respectively.

h. **Leases:** All of our leases are operating leases and are included in right-of-use lease assets, current lease liabilities and noncurrent lease liabilities on our condensed consolidated balance sheets. These assets and liabilities are recognized at the commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates or implicit rates, when readily determinable. The discount rates used for each lease were based principally on the Platinum debt, which was secured and outstanding for most of 2018. We used a "build-up" method where the approach was to estimate the risk/credit spread priced into the debt rate and then adjust that for the remaining term of each lease. Additionally, some market research was completed on the Company's peer group. Short-term operating leases which have an initial term of 12 months or less are not recorded on the condensed consolidated balance sheets. Lease expense for operating leases is recognized on a straight-and line basis over the lease term. Lease expense is included in selling, general and administrative expenses on our condensed consolidated statements of operations. See Note 9.

i. **Contingent Liabilities:** We are subject to legal proceedings and claims that arise in the normal course of business. In accordance with ASC Topic 450, *Contingencies*, we accrue for contingent liabilities when management determines it is probable that a liability has been incurred and the amount can be reasonably estimated. This determination requires significant judgment by management. As of the date of the filing of this Quarterly Report on Form 10-Q, we are engaged in separate matters of ongoing litigation with Capital Royalty Partners II, L.P. ("CRG") and our former President and Chief Executive Officer, Dr. Michael Goldberg. See Note 10.

j. **Recently Adopted Accounting Standards:** In June 2016, the Financial Accounting Standards Board ("FASB") Issued Accounting Standards Update ("ASU") No. 2016-13, *Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 was issued to provide financial statement users with more useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. ASU 2016-13 requires a financial asset (or group of financial assets) measured at amortized cost to be presented at the net amount expected to be collected. In addition, credit losses related to available-for-sale debt securities should be recorded through an allowance for credit losses. The amendments in ASU 2016-13 are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early application of the amendments is permitted. An entity should apply the amendments in ASU 2016-13 through a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective (a modified-retrospective approach). The adoption of ASU 2016-13 did not have a material impact on our condensed consolidated financial statements.

2. Liquidity

The Company is engaged in ongoing litigation with CRG. On August 30, 2022, the District Court of Harris County, Texas (the "Texas Court") awarded CRG approximately $2.6 million in attorney's fees on their breach of contract claims against Navidea and MT, subject to an interest rate of 18% per annum. The Company has appealed the Texas Court's judgment to the Fourteenth Court of Appeals of Texas. As of March 31, 2023, the Company has accrued $3,500,011 of legal fees and interest pursuant to the Texas Court's ruling. See Note 10.

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

The Company has previously entered into an API Development Funding and Access Agreement ("API Development Agreement") with a strategic partner for assistance with the development and supply of the active pharmaceutical ingredient ("API") used to manufacture Lymphoseek (technetium Tc 99m tilmanocept) that is sold by the Company in countries other than the United States, Canada and Mexico. Under the API Development Agreement, among other things, the strategic partner agreed to reimburse the Company for up to a total of $1.85 million of the Company's out-of-pocket costs associated with such development, in two installments, subject to specified commercial and regulatory milestones. On August 11, 2022, the Company received the first installment in the amount of $800,000, which the strategic partner has the right to claw back due to the Company not satisfying certain commercial and regulatory milestones on or before March 31, 2023. The Company remains engaged in consistent communication with the strategic partner regarding this issue and the status of the API Development process. Based on these communications and the strategic partner's expressed desire and financial and operational motivation for successful completion of the API Development process, the Company does not expect the strategic partner to exercise its claw-back right. The strategic partner is obligated, subject to certain conditions, to pay the remaining reimbursement amount upon the later of July 1, 2023 or satisfaction of specified commercial and regulatory milestones.

The current conflict between Ukraine and Russia has created volatility in the global capital markets and is continuing to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties who operate in Europe on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any debt or equity financing more difficult to obtain, more costly or more dilutive.

The Company has experienced recurring net losses and has used significant cash to fund its operations. The Company has considerable discretion over the extent of development project expenditures and has the ability to curtail the related cash flows as needed. The Company also continues working to establish new sources of funding, including potential equity and/or debt financings, collaborations and additional grant funding that can augment the balance sheet. However, based on our current working capital and our projected cash burn, management believes that there is substantial doubt about the Company's ability to continue as a going concern for a period of one year from the filing of this Quarterly Report on Form 10-Q.

3. Revenue from Contracts with Customers and Other Revenue

Navidea is focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. We manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform, and (ii) therapeutic development programs, including all therapeutic applications of our Manocept platform. Tc99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, is the only one of the Company's drug product candidates that has been approved for sale in any market. Tc99 tilmanocept has only been approved for sale in the European Union ("EU"), the UK, India and Australia.

We earn revenue from product sales to end customers, primarily in Europe. Revenue from product sales is generally recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which occurs upon either shipment of the product or arrival at its destination, depending upon the shipping terms of the transaction. 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. Normal payment terms generally range from 30 to 90 days from invoice date, in accordance with each contract or purchase order.

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

Up-front and milestone payments received related to our license and distribution agreements in India and China are deferred until Tc99m tilmanocept has been approved by the regulatory authorities and product sales are authorized to commence in each of those countries. The Company received regulatory approval for Tc99m tilmanocept in India in late March 2022, however certain additional approvals, such as an import license and authorization to use an alternative manufacturer, must be obtained prior to commercial sales launch in India. It is not possible to determine with any degree of certainty whether or when regulatory approval for this product will be achieved in China, if at all. In addition, since sales of Tc99m tilmanocept have not yet begun in India or China, there is no basis for estimating whether, to what degree, or the rate at which the product will be accepted and utilized in these markets. Therefore, it is not possible to determine with any degree of certainty the expected sales in future periods in those countries. As such, the Company intends to recognize revenue from up-front and milestone payments on a straight-line basis beginning at the time of commercial sales launch in each country through the end of the initial term of each agreement. The initial term of each agreement is eight years in India and ten years in China.

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

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

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

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

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

During the three-month periods ended March 31, 2023 and 2022, the Company recognized revenue from contracts with customers of $0. During the three-month periods ended March 31, 2023 and 2022, the Company did not recognize any related impairment losses, nor did the Company recognize any revenue from performance obligations associated with long-term contracts that were satisfied (or partially satisfied) in previous periods.

The following table disaggregates the Company's revenue from contracts with customers for the three-month periods ended March 31, 2023 and 2022.

	Three Months Ended March 31,	
	2023	**2022**
License revenue:		
	$ —	$ —
Sales revenue:		
	$ —	$ —

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

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

Status of Regulatory Approval. The majority of revenue from contracts with customers will generally be recognized after the product is approved for sale in each market. Each Tc99m tilmanocept customer operates in its own distinct regulatory environment, and the laws and pathways to drug product approval vary by market. Tc99m tilmanocept has been approved for sale in the EU and the UK, thus the Company recognized revenue from sales in Europe. Tc99m tilmanocept was approved for sale in India in March 2022, however product sales have not yet commenced. Tc99m tilmanocept has not yet been approved for sale in China and may never achieve approval in that market. The regulatory pathways and timelines in China will impact whether and when the Company recognizes the related royalties and milestones.

Through March 31, 2023, the Company has not capitalized any contract-related costs as contract assets.

The following table shows the opening and closing balances of contract liabilities from contracts with customers for the the three-month period ended March 31, 2023.

	March 31, 2023 (unaudited)	**December 31, 2022**
Total deferred revenue related to contracts with customers, beginning of period	$ 700,000	$ 700,000
Deferred revenue related to milestones achieved	—	—
Total deferred revenue, end of period	$ 700,000	$ 700,000

The Company had sales revenue receivable of $0 and $610 outstanding as of March 31, 2023 and December 31, 2022, respectively. The Company had license revenue receivable of $0 outstanding as of March 31, 2023 and December 31, 2022.

In addition to revenue from contracts with customers, we also generate revenue from National Institutes of Health ("NIH") grants to support various product development initiatives. The revenue recognition standard applies to revenue from contracts with customers. A customer is defined as a party that has contracted with an entity to obtain goods or services that are an output of the entity's ongoing major or central operations in exchange for consideration. The Company's ongoing major or central operations consist of the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. The NIH and its various institutes are responsible for biomedical and public health research and provide major biomedical research funding to non-NIH research facilities and entities such as Navidea. While the Company will directly benefit from any knowledge gained from the project, there is also a public health benefit provided, which justifies the use of public funds in the form of the grants. Based on the nature of the Company's operations and the terms of the grant awards, Navidea does not have a vendor-customer relationship with the NIH and the grant awards are outside the scope of the revenue recognition standard. Accordingly, the revenue recognition standard need not be applied to the NIH grants. During the three-month periods ended March 31, 2023 and 2022, the Company recognized grant revenue of $0.

Finally, we expect to recognize revenue from a strategic development partner up to a total of $1.85 million under the terms of the API Development Agreement. Based on the nature of the Company's operations and the terms of the API Development Agreement, Navidea does not have a vendor-customer relationship with the strategic partner and amounts received under the API Development Agreement are outside the scope of the revenue recognition standard. Accordingly, the revenue recognition standard need not be applied to the API Development Agreement. The first installment of $800,000 received on August 11, 2022 was included in deferred revenue, current in the condensed consolidated balance sheets as of March 31,2023. See Note 2.

4. Stock-Based Compensation

For the three-month periods ended March 31, 2023 and 2022, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was $19,669 and $184,850, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-

month periods ended March 31, 2023 and 2022.

A summary of the status of our stock options as of March 31, 2023, and changes during the three-month period then ended, is presented below.

	Three Months Ended March 31, 2023			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2023	702,805	$ 4.42	5.5	$ —
Granted	1,339,500	0.32		
Cancelled/Forfeited	(138,350)	1.04		
Expired	(850)	61.60		
Outstanding, March 31, 2023	1,903,105	$ 1.75	8.2	$ —
Exercisable, March 31, 2023	569,231	$ 4.92	4.5	$ —

The weighted average grant date fair value per stock option granted during the three-month period ended March 31, 2023 was $0.24. Key assumptions used in the Black-Scholes option pricing model for stock options granted during the three-month period ended March 31, 2023 were the Company's stock price, an expected volatility rate of 89.47%, a risk-free rate of 3.87%, and an expected life of 5.95 years.

A summary of the status of our unvested restricted stock as of March 31, 2023, and changes during the three-month period then ended, is presented below.

	Three Months Ended March 31, 2023	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested, January 1, 2023	90,000	$ 0.99
Vested	—	—
Unvested, March 31, 2023	90,000	$ 0.99

As of March 31, 2023, there was $315,029 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 1.95 years.

5. Loss Per Share

Diluted loss per common share for the three-month periods ended March 31, 2023 and 2022 excludes the effects of 25,267,071 and 1,310,974 common share equivalents, respectively, since such inclusion would be anti-dilutive. The excluded shares consist of common shares issuable upon exercise of outstanding stock options and warrants.

The Company's unvested restricted stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as "participating securities"). Therefore, the unvested restricted 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, 90,000 and 92,500 shares of unvested restricted stock for the three-month periods ended March 31, 2023 and 2022, respectively, were excluded in determining basic and diluted loss per share from continuing operations because such inclusion would be anti-dilutive.

6. Inventory, Net

The components of inventory, net as of March 31, 2023 and December 31, 2022 are as follows:

	March 31, 2023	December 31. 2022
Materials	$ 27,405	$ 27,405
Work in process	433,231	399,939
Finished goods	131,804	131,804
Reserve for expiring finished goods	(131,804)	(131,804)
Total inventory, net	$ 460,636	$ 427,344

During the three-month periods ended March 31, 2023 and 2022, we allocated $0 and $4,054, respectively, of finished goods inventory for use in clinical trials. These transactions were recorded in research and development expense in the condensed consolidated statements of operations.

7. Accounts Payable, Accrued Liabilities and Other

Accounts payable as of March 31, 2023 and December 31, 2022 includes an aggregate of $427,069 and $318,527, respectively, due to related parties for director fees and interest on notes payable. Accrued liabilities and other as of March 31, 2023 and December 31, 2022 includes an aggregate of $609,104 and $811,544, respectively, due to related parties for accrued separation costs, bonuses, benefits, and director fees.

The Company pays director fees in both cash and stock. The cash portion of director fees due is included in accounts payable and the stock portion is included in accrued liabilities and other in the condensed consolidated balance sheet as of March 31, 2023 and December 31, 2022. Certain directors have elected to defer receipt of cash and stock for director fees until the Company raises sufficient additional capital.

Under our license agreements with the University of California, San Diego (“UCSD”), we have exclusive world-wide rights to all diagnostic and therapeutic uses of tilmanocept, other than Tc99m tilmanocept used in lymphatic mapping in the United States, Canada and Mexico which rights are licensed to Cardinal Health 414. The UCSD license agreements include obligations for payments related to license fees, milestones, and royalties. As of March 31, 2023, the Company has accrued approximately $259,000 related to the UCSD license agreements for which we have not yet been invoiced. Of this amount, approximately $104,000 is included in accounts payable and $155,000 is included in accrued expenses and other in the condensed consolidated balance sheets. During the quarter ended March 31,2023, the Company reversed approximately $1.2 million of accruals due to an amendment of the UCSD license agreement for the exclusive world-wide rights to all diagnostic and therapeutic uses of tilmanocept (other than Tc99m tilmanocept used in lymphatic mapping).

On March 30, 2023 (the “Effective Date”), Dr. Michael Rosol signed a Separation & Release Agreement (the “Separation Agreement”) in connection with his resignation from his position as Chief Medical Officer on April 10, 2023 (the “Separation Date”). Pursuant to the Separation Agreement, among other things, the Company agreed to pay Dr. Rosol a lump sum payment, less all relevant taxes and other withholdings, of $25,000, payable pursuant to normal payroll processes upon the Effective Date. This amount, plus the related employer tax liability, is included in the accrued separation costs described above. For purposes of assistance provided to facilitate the smooth transition of the operation and management of the Company for a period of 6 months after the Separation Date, the Company agreed to pay Dr. Rosol $300 per hour, subject to certain limitations. In addition, Dr. Rosol and the Company generally released each other from any and all claims each may have against the other.

On March 30, 2023, in conjunction with Dr. Rosol’s separation, the Company entered into a Consulting Services Agreement (“Consulting Agreement”) with G2G Ventures (“G2G”), the executive director of which is Joshua Wilson, a director of the Company. Under the Consulting Agreement, G2G will provide executive-level support services to the Company as mutually agreed in one or more statements of work. The Company will pay G2G a monthly retainer of $50,000. The Consulting Agreement may be terminated by either party upon 90 days’ notice.

8. Notes Payable

Bridge Note from John K. Scott, Jr.

On April 10, 2022, the Company entered into a Stock Exchange Agreement with John K. Scott, Jr., pursuant to which Mr. Scott agreed to make a loan to the Company in the principal amount of up to $2.5 million, of which $1.5 million was funded on the closing date and $1.0 million was funded on July 1, 2022. The outstanding balance of the loan, which is evidenced by a bridge note (“2022 Bridge Note”), bears interest at a rate of 8% per annum, with payments of interest only to be made monthly over a period of two years. All outstanding principal and accrued and unpaid interest under the 2022 Bridge Note is due and payable on the second anniversary of the Stock Exchange Agreement. The Company’s obligations under the 2022 Bridge Note are secured by a first priority security interest in all of the Company’s assets and personal property pursuant to a Security Agreement.

As consideration and partial inducement for Mr. Scott to enter into the 2022 Bridge Note, the Company exchanged all 50,000 shares of Mr. Scott's Series E Preferred Stock for 1,740 shares of Series F Preferred Stock and 3,260 shares of Series G Preferred Stock. In accordance with current accounting guidance, the Company recorded a debt discount of $835,876 including $821,250 related to the difference in the value of Mr. Scott's Series E Preferred Stock and the Series F and Series G Preferred Stock and $14,626 of debt issuance costs. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the 2022 Bridge Note. The balance of the debt discount was $536,134 as of March 31, 2023.

Interest expense related to the Bridge Note totaled $142,151 during the three-month period ended March 31, 2023. The principal balance of the 2022 Bridge Note was $2.5 million as of March 31, 2023.

IPFS Corporation

In November 2021, we prepaid $565,760 of insurance premiums through the issuance of a note payable to IPFS Corporation ("IPFS") with an interest rate of 4.36%. The note was payable in five monthly installments of $114,388, with the final payment made in April 2022.

Interest expense related to the IPFS note payable totaled $0 and $3,712 during the three-month periods ended March 31, 2023 and 2022, respectively. The balance of the IPFS note was $0 as of March 31, 2023.

AFCO Premium Credit LLC

In November 2022, we prepaid $608,275 of insurance premiums through the issuance of a note payable to AFCO Premium Credit LLC ("AFCO") with an interest rate of 7.85%. The note is payable in nine monthly installments of $69,967, with the final payment due in August 2023.

Interest expense related to the AFCO note payable totaled $9,362 and $0 during the three-month periods ended March 31, 2023 and 2022, respectively. The balance of the AFCO note was $343,074 as of March 31, 2023, and was included in notes payable, current in the condensed consolidated balance sheets.

Summary

During the three-month periods ended March 31, 2023 and 2022, we recorded interest expense of $151,514 and $3,712, respectively, related to our notes payable. Annual principal maturities of our notes payable are $343,074 and $2.5 million in 2023 and 2024, respectively.

9. Leases

We currently lease approximately 5,000 square feet of office space at 4995 Bradenton Avenue, Dublin, Ohio, as our principal offices, at a monthly base rent of approximately $3,012. The current least term expires in June 2023.

In addition, we leased approximately 25,000 square feet of office space at 5600 Blazer Parkway, Dublin, Ohio, formerly our principal offices, at a monthly base rent of $28,149 in 2022. The lease term expired in October 2022 with an option to extend for an additional five years. The Company did not renew this lease. In June 2017, the Company executed a sublease arrangement for the Blazer Parkway space, providing for monthly sublease payments to Navidea of $39,124 through October 2022.

We currently lease office equipment at a monthly payment of $136, expiring in October 2024.

Total operating lease expense was $9,449 and $37,676 for the three-month periods ended March 31, 2023 and 2022, respectively, and was recorded in selling, general and administrative expenses on our condensed consolidated statements of operations.

The following table presents information about the amount, timing and uncertainty of cash flows arising from the Company's operating leases as of March 31, 2023.

Maturity of Lease Liabilities	Operating Lease Payments
2023 (remaining)	$ 10,256
2024	1,355
Total undiscounted operating lease payments	11,611
Less imputed interest	313
Present value of operating lease liabilities	$ 11,298
Balance Sheet Classification	
Current lease liabilities	$ 10,372
Noncurrent lease liabilities	926
Total operating lease liabilities	$ 11,298
Other Information	
Weighted-average remaining lease term for operating leases (in years)	0.5
Weighted-average discount rate for operating leases	10.22%

Cash paid for amounts included in the present value of operating lease liabilities was $9,443 and $93,889 during the three-month periods ended March 31, 2023 and 2022, respectively, and is included in operating cash flows in the condensed consolidated statements of cash flows.

10. Commitments and Contingencies

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

CRG Litigation

The Company has been engaged in ongoing litigation with CRG, in its capacity as a lender and as control agent for other affiliated lenders party to the CRG Loan Agreement (collectively, the "CRG Lenders"), in the Texas Court relating to CRG's claims of default under the terms the CRG Loan Agreement. Following a trial in December 2017, the Texas Court ruled that the Company's total obligation to CRG was in excess of $66.0 million, limited to $66.0 million under the Global Settlement Agreement ("GSA") dated March 3, 2017. The Texas Court acknowledged only the $59.0 million payment made in March 2017, concluding that the Company owed CRG another $7.0 million, however the Texas Court did not expressly take the Company's June 2016 payment of $4.1 million into account and awarded, as part of the $66.0 million, amounts that had already been paid as part of the $4.1 million. The Company believes that this $4.1 million should be credited against the $7.0 million and has appealed the Texas Court's judgment. The Court of Appeals dismissed the Company's appeal without reaching the merits due to a contractual waiver of appeal.

In April 2018, CRG asserted claims against Navidea and MT for alleged breaches of the GSA and Loan Agreement entered into by Navidea arising from Navidea's challenge to CRG's drawing down on letters of credit in the full amount of $7,153,000. Navidea claimed such draw down resulted in an overpayment of approximately $4.2 million under the Loan Agreement. CRG also sought declaratory judgment relief that essentially mirrored their claims for affirmative relief, i.e., that the Company breached the GSA and indemnification provision of the Loan Agreement, and that CRG did not breach the GSA.

On November 21, 2021, the Texas Court entered an interlocutory judgment declaring that CRG did not breach the GSA, but that Navidea did breach the GSA and the indemnification provision of the CRG Loan Agreement. In the interlocutory order, the Texas Court sua sponte awarded as damages reasonable attorneys' fees in an amount, if any, to be determined at trial. CRG made a claim of approximately $2.8 million in attorneys' fees they contend they are entitled to in connection with the alleged breaches of the agreements. Navidea contends CRG have received payments in excess of the amounts owed under the CRG Loan Agreement and are not entitled to an award of attorney's fees under the GSA or Loan Agreement. On August 30, 2022, the Texas Court made an oral ruling from the bench at the conclusion of the trial, awarding CRG approximately $2.6 million in attorney's fees on their breach of contract claims against Navidea and MT. A formal written final judgment was entered by the Texas Court on August 31, 2022, however, the written judgment did not identify the basis and reasoning in support of the decision. On September 9, 2022 Navidea filed a request for findings of fact and conclusions of law, asking that the Texas Court state in writing the facts found by the Court and the Court's conclusions of law. On October 11, 2022, the Texas Court filed their findings of fact and conclusions of law, which includes conclusions of law that the amounts due are subject to an interest rate of 18% per annum. The Company has objected to many of the findings of fact and conclusions of law and to any attempt to amend the final judgment as being untimely. The Texas Court's judgment remains unchanged. The Company has appealed the Texas Court's judgment to the Fourteenth Court of Appeals of Texas, filing its Appellant's Brief on April 7, 2023. As of March 31, 2023, the Company has accrued approximately $3.5 million of legal fees and interest pursuant to the Texas Court's ruling.

Goldberg Agreement and Litigation

In August 2018, Dr. Goldberg resigned from his positions as an executive officer and a director of Navidea. In connection with Dr. Goldberg's resignation, Navidea and Dr. Goldberg entered into an Agreement (the "Goldberg Agreement") which set forth the terms of the separation from service. Among other things, the Goldberg Agreement provided that Dr. Goldberg would be entitled to 1,175,000 shares of our Common Stock, representing in part payment of accrued bonuses and payment of the balance of the Platinum debt. A portion of the 1,175,000 shares to be issued to Dr. Goldberg would be held in escrow for up to 18 months in order to reimburse Navidea in the event that Navidea is obligated to pay any portion of the Platinum debt to a party other than Dr. Goldberg. Further, the Goldberg Agreement provided that the Company's subsidiary, MT, would redeem all of Dr. Goldberg's preferred stock and issue to Dr. Goldberg super voting common stock equal to 5% of the outstanding shares of MT. In November 2018, the Company issued 925,000 shares of our Common Stock to Dr. Goldberg, 250,000 of which were placed in escrow in accordance with the Goldberg Agreement.

On February 11, 2019, Dr. Goldberg represented to the MT Board of Directors (the "MT Board") that he had, without MT Board or shareholder approval, created a subsidiary of MT, transferred all of the assets of MT into the subsidiary, and then issued himself stock in the subsidiary. On February 19, 2019, Navidea notified MT that it was terminating the sublicense in accordance with its terms, effective March 1, 2019, due to MT's insolvency. On February 20, 2019, the MT Board removed Dr. Goldberg as President and Chief Executive Officer of MT and from any other office of MT to which he may have been appointed or in which he was serving. Dr. Goldberg remains a member of the MT Board, together with John K. Scott, Jr., who is also the Vice Chair of the Board of Directors of Navidea. On or about February 17, 2022, the Joint Official Liquidators and Foreign Representatives of PPVA executed the necessary paperwork to transfer its preferred stock in MT to Navidea.

New York Litigation Involving Dr. Goldberg

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

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

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

In addition, the District Court found Navidea's breach of fiduciary duty claim against Dr. Goldberg for conduct occurring more than three years prior to the filing of the complaint to be time-barred and that Dr. Goldberg is entitled to an advancement of attorneys' fees solely with respect to that claim. To avoid further litigation expenses, the Company agreed to indemnify Dr. Goldberg solely with respect to the breach of fiduciary duty claim.

On January 31, 2020, Goldberg filed a motion for leave to amend his complaint to add back in claims for breach of contract, breach of the implied covenant of good faith and fair dealing, quantum meruit and injunctive relief. On April 1, 2020, the District Court denied Dr. Goldberg's motion for leave to amend in its entirety.

On January 27, 2020, Dr. Goldberg filed a motion seeking additional advancement from Navidea for fees in connection with the New York Action and the Delaware Action. Navidea opposed the motion and the District Court referred the matters to a Magistrate Judge. On July 9, 2020, the Magistrate Judge issued her Report and Recommendation which recommended that: (1) the District Court decline to exercise jurisdiction over Dr. Goldberg's motion as it pertained to expenses and fees incurred in defense of the Delaware Action; (2) the District Court decline to award any fees to Dr. Goldberg for the breach of fiduciary duty without additional motion practice on the issue; (3) the District Court find that Dr. Goldberg is entitled to advancement of his expenses and fees reasonably incurred in the defense of the remainder of the New York action subject to Dr. Goldberg's posting of an undertaking; and (4) establish a protocol by which Dr. Goldberg could establish the amounts due for advancement.

On August 24, 2020, in connection with Dr. Goldberg's motion for advancement, the District Court adopted the Magistrate Judge's report and recommendation and found that while Dr. Goldberg was not being granted advancement of fees and expenses incurred in connection with either the Delaware Action or the assertion of third-party claims against MT, the Court ruled that Dr. Goldberg was entitled to advancement for the defense of the remaining claims asserted against him by Navidea in the New York action. The Court adopted a protocol by which additional motion practice will occur to determine the appropriate amount of fees to be advanced. Once that decision is made by the Magistrate Judge, subject to review by the District Court, Navidea will need to advance those fees to Dr. Goldberg conditioned upon Dr. Goldberg agreeing to pay those fees back to Navidea if it is determined that he is not entitled to indemnification.

On May 27, 2021, the District Court ordered that: (1) Dr. Goldberg be awarded $14,955 for indemnification for his attorneys' fees for his defense of the breach of fiduciary duty claim; (2) Dr. Goldberg be advanced $1,237.50 for his attorneys' fees subject to repayment; (3) Navidea should not be required to indemnify or advance any of the costs sought by Dr. Goldberg; (4) Dr. Goldberg is not entitled to advancement for the prosecution of his counterclaims and third-party claims; (5) Dr. Goldberg's motion to hold Navidea in contempt be denied; and (6) Navidea should not be required to advance any additional fees or costs unless Dr. Goldberg presents his time records and costs in compliance with the District Court's orders. The Company has made the payments ordered by the District Court.

On August 6, 2021, the Company moved for reconsideration of its obligations to advance fees. On October 14, 2021, the Magistrate Judge recommended that Navidea's motion for reconsideration be denied. On March 7, 2022, the District Court adopted the Report and Recommendation in part and permitted Dr. Goldberg to seek advancement for his fees incurred in defense of his claims since September 1, 2020. On April 8, 2022, Dr. Goldberg submitted a fee application seeking advancement of $143,172.55 for attorneys' fees and disbursements for the time period September 1, 2020 through March 31, 2022. On March 15, 2023, the District Court adopted the Magistrate Judge's report and recommendation that Dr. Goldberg's application for fees allegedly incurred in connection with his defense of Navidea's claims be denied as a sanction for failure to comply with prior court orders and that his application for fees incurred in connection with the successful prosecution of his prior fee applications be approved in the amount of $12,600. On March 17, 2023, the District Court confirmed that no further claims for advancement will be accepted by the Court in light of its March 15, 2023 Order. The Company has made the payment ordered by the District Court.

Fact discovery and expert discovery in the New York Action have been completed. The Company moved to disqualify Dr. Goldberg's damages expert. On November 9, 2022, the District Court issued an opinion granting the Company's motion in part and precluding Dr. Goldberg's damages expert from testifying on all but two issues. The Court has set a deadline of July 13, 2023 for the time by which the parties must submit their motions for summary judgment.

NYSE American Continued Listing Standards

On January 28, 2022, the Company received a notification from the NYSE American LLC (the "NYSE American") stating that the Company was not in compliance the $6.0 million stockholders' equity requirement of Section 1003(a)(iii) of the NYSE American Company Guide. As required by the NYSE American, the Company submitted a plan to the NYSE American by February 28, 2022 advising of actions it has taken or will take to regain compliance with the continued listing standards by July 28, 2023.

On April 8, 2022, the Company received a notification (the "Acceptance Letter") from the NYSE American that the Company's plan to regain compliance was accepted. The Acceptance Letter also stated that the Company is also not in compliance with Sections 1003(a)(i) and 1003(a)(ii) of the NYSE American Company Guide, which require an issuer to have stockholders' equity of (i) $2.0 million or more if it has reported losses from continuing operations and/or net losses in two out of its three most recent fiscal years, and (ii) $4.0 million or more if it has reported losses from continuing operations in three out of its four most recent fiscal years. The Acceptance Letter noted that the Company had stockholders' equity of $624,743 as of December 31, 2021 and has reported net losses from continuing operations in its five most recent fiscal years ended December 31, 2021.

The NYSE American has granted the Company a plan period through July 28, 2023 to regain compliance with Sections 1003(a)(i), (ii) and (iii). If the Company is not in compliance with all continued listing standards by that date or if the Company does not make progress consistent with the plan during the plan period, the NYSE American may commence delisting procedures.

11. Equity

Amendment to NOL Rights Agreement

On April 7, 2022, the Company's Board of Directors (the "Board") adopted an NOL rights plan in the form of a Section 382 Rights Agreement ("NOL Rights Agreement") to preserve and protect the Company's net operating loss carryforwards ("NOLs") and other tax assets. As of December 31, 2022, the Company had approximately $175 million of NOLs available to offset future federal taxable income.

Under the NOL Rights Agreement, the Board declared a non-taxable dividend of one preferred share purchase right for each outstanding share of common stock of the Company, each right initially representing the right to purchase one one-thousandth of a share of our Series H Junior Participating Preferred Stock. The rights will be exercisable only if a person or group acquires 4.99% or more of Navidea common stock. Existing shareholders that beneficially own in excess of 4.99% of Navidea common stock are "grandfathered in" at their current ownership level and the rights then become exercisable if any of those stockholders acquire an additional 0.5% or more of Navidea common stock. If the rights become exercisable, all holders of rights, other than the person or group triggering the rights, will be entitled to purchase Navidea common stock at a 50 percent discount or the Company may exchange each right held by such holders for five shares of common stock (the "Exchange Ratio"). Rights held by the person or group triggering the rights will become void and will not be exercisable. The Board has the discretion to exempt any person or group from the provisions of the NOL Rights Agreement.

On January 10, 2023, the Board approved the First Amendment to Section 382 Rights Agreement ("NOL Rights Agreement Amendment"), which reduced the Exchange Ratio from five shares of common stock per right to three shares of common stock per right. No other terms of the NOL Rights Agreement were amended.

The rights issued under the NOL Rights Agreement, as amended, will expire on the earliest of (i) April 6, 2025; (ii) the effective date of the repeal of Section 382 or any successor statute if the Board determines in its sole discretion that the amended NOL Rights Agreement is no longer necessary or desirable for the preservation of NOLs or other tax benefits; (iii) the first day of a taxable year of the Company to which the Board determines in its sole discretion that no NOLs or other Tax Benefits may be carried forward; or (iv) the day following the certification of the voting results of the Company's 2022 annual meeting of stockholders if at or before such annual meeting a proposal to approve the NOL Rights Agreement has not been approved by stockholders, unless the Rights are earlier redeemed or exchanged by the Company, or upon the occurrence of certain transactions.

401(k) Employer Match

During the three-month periods ended March 31, 2023 and 2022, we issued 163,586 and 53,238 shares of our Common Stock as matching contributions to our 401(k) Plan, which were valued at $52,348 and $44,720, respectively.

Long Term Incentive Plan

On September 9, 2022, the Company's Board of Directors (the "Board") approved and adopted the terms and conditions of a long-term incentive plan ("LTIP") that seeks to motivate and reward employees. The LTIP provides for the issuance of share-based awards to employees of the Company pursuant to the 2014 Plan. The target amount of the stock award under the LTIP for each employee was determined based on a variety of factors. Payout of the stock awards is based on the achievement of pre-established performance objectives and goals related to financing and U.S. Food and Drug Administration ("FDA") and European Medicines Agency ("EMA") regulatory milestones for the Company's Phase 3 clinical trial for rheumatoid arthritis (NAV3-33). The financing and EMA regulatory milestones will each comprise 5% of the total stock award payout for participants; the FDA regulatory milestones will comprise the remaining 90%. The payout amount is subject to downward adjustment based on the timing of the achievement of the particular milestone. In order to receive the payout, the participant generally will be required to continue to be employed through the date of the payout.

Although the Company did not fully satisfy the financing milestone, based on completion of the Rights Offering in August 2022 ("2022 Rights Offering"), the Board decided to pay out 5% of the target stock award to all participants under the LTIP. During the year ended December 31, 2022, we issued 70,500 shares of Common Stock to all participants under the LTIP, which were valued at $19,740. Upon issuance of the stock awards, the participants were 100% vested in the stock awards.

On March 10, 2023, the Board amended the LTIP to award all 1,339,500 remaining unearned LTIP stock awards as stock options. The LTIP stock options have an exercise price of $0.32 per share and will expire on the tenth anniversary of the date of grant. The LTIP stock options will vest according to the performance objectives originally established for the LTIP as described above.

12. Stock Warrants

As of March 31, 2023, there are warrants outstanding to purchase 23,363,966 shares of Common Stock. The warrants are exercisable at prices ranging from $0.50 to $49.80 per share with a weighted average exercise price per share of $0.54. The warrants have remaining outstanding terms ranging from 0.2 to 4.4 years.

13. Income Taxes

Income taxes are accounted for under the asset and liability method in accordance with Accounting Standards Codification 740, *Income Taxes*. Deferred tax assets ("DTAs") and deferred tax liabilities ("DTLs") 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. DTAs and DTLs 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 DTAs and DTLs of a change in tax rates is recognized in income in the period that includes the enactment date.

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 as of March 31, 2023 and December 31, 2022.

In assessing the realizability of DTAs, management considers whether it is more likely than not that some portion or all of the DTAs will not be realized. The ultimate realization of DTAs is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods) and projected future taxable income in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the DTAs are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences or tax carryforwards as of March 31, 2023.

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 March 31, 2023 or December 31, 2022 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 March 31, 2023, tax years 2019-2022 remained subject to examination by federal and state tax authorities.

As of March 31, 2023, we had approximately $175.1 million of federal and $20.1 million of state net operating loss carryforwards, as well as approximately $9.1 million of federal R&D credit carryforwards which expire from 2023 to 2037.

14. Segments

We report information about our operating segments using the "management approach" in accordance with current accounting standards. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. We manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform, and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform.

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

Three Months Ended March 31, 2023	Diagnostics	Therapeutics	Corporate	Total
Research and development expenses	$ 1,170,553	$ 96,900	$ —	$ 1,267,453
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	2,178	1,125,183	1,127,361
Depreciation and amortization (2)	9,275	—	18,280	27,555
Loss from operations (3)	(1,179,828)	(99,078)	(1,143,463)	(2,422,369)
Other expense (4)	—	—	946,039	946,039
Net loss	(1,179,828)	(90,078)	(197,424)	(1,476,330)
Total assets, net of depreciation and amortization:				
United States	$ —	$ —	$ 1,776,386	$ 1,776,386
International	578,272	—	12,928	591,200
Capital expenditures	15,068	—	—	15,068

Three Months Ended March 31, 2022	Diagnostics	Therapeutics	Corporate	Total
Research and development expenses	$ 989,887	$ 179,367	$ —	$ 1,169,254
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	—	1,787,152	1,787,152
Depreciation and amortization (2)	6,040	—	16,838	22,878
Loss from operations (3)	(995,927)	(179,367)	(1,803,990)	(2,979,284)
Other expense (4)	—	—	(7,961)	(7,961)
Net loss	(995,927)	(179,367)	(1,811,951)	(2,987,245)
Total assets, net of depreciation and amortization:				
United States	$ 150,920	$ —	$ 3,034,316	$ 3,185,236
International	393,753	—	23,136	416,889
Capital expenditures	40,221	—	1,796	42,017

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

(2) Depreciation and amortization are reflected in selling, general and administrative expenses ($27,555 and $22,878 for the three-month periods ended March 31, 2023 and 2022, respectively).

(3) Loss from operations does not reflect the allocation of certain selling, general and administrative expenses, excluding depreciation and amortization, to our individual reportable segments, other than those expenses directly incurred by Navidea Europe, Navidea UK and MT.

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

15. Supplemental Disclosure for Statements of Cash Flows

During the three-month periods ended March 31, 2023 and 2022, we paid interest aggregating $117,810 and $3,712, respectively. During the three-month periods ended March 31, 2023 and 2022, we issued 163,586 and 53,238 shares of our Common Stock as matching contributions to our 401(k) Plan, which were valued at $52,348 and $44,720, respectively.

16. Subsequent Events

The Company has evaluated events and transactions subsequent to March 31, 2023 and through the date these condensed consolidated financial statements were included in this Quarterly Report on Form 10-Q and filed with the SEC.

Asset Purchase Agreement

On April 10, 2023, the Company entered into an Asset Purchase Agreement with Meilleur Technologies, Inc. ("Meilleur"), pursuant to which Meilleur agreed to acquire certain assets and assume certain liabilities of the Company relating to its business of developing and commercializing PET biomarkers for Alzheimer's Disease (the "Business"). As part of the purchase price, Meilleur paid a cash payment of $250,000 to the Company at closing and agreed to make a cash payment of $500,000 to the Company within 60 days after the closing date. In addition, Meilleur agreed to make certain future payments (as part of the purchase price) to the Company, including contingent payments and milestone payments based on potential licensing events, regulatory submissions, regulatory approvals, and net sales of any approved product derived from the purchased Business.

Bridge Note from John K. Scott, Jr.

On April 25, 2023, Mr. Scott agreed to make a second loan to the Company in the principal amount of up to $300,000 under the terms of a secured bridge note ("2023 Bridge Note"), of which $225,000 and $75,000 were funded on April 26, 2023. and May 9, 2023, respectively. The Company has agreed to pay a non-refundable fee of $15,000 to Mr. Scott at maturity on June 26, 2023. The Company's obligations under the 2023 Bridge Note are secured by a first priority security interest in all of the Company's assets and personal property pursuant to the Security Agreement dated April 10, 2022, as amended on April 25, 2023 in favor of Mr. Scott.

Stock Purchase Agreement

On April 26, 2023, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with Keystone Capital Partners, LLC ("Keystone") whereby the Company may offer and sell, from time to time at its sole discretion, and whereby Keystone committed to purchase, up to $2,750,000 of shares of the Company's common stock (but subject to certain limitations and conditions). Under the Purchase Agreement, the Company agreed to issue to Keystone 400,000 shares of Common Stock as consideration for its commitment to purchase shares under the Purchase agreement, with 200,000 shares (based on the closing stock price of $0.25 as of April 25, 2023) being delivered on the date of the Purchase Agreement and the remaining 200,000 shares (based on the closing stock price of $0.25 as of April 25, 2023) to be delivered upon the Company raising a minimum of $2,750,000 under the Purchase Agreement or any other source. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Keystone, pursuant to which it agreed to provide Keystone with certain registration rights related to the shares issued under the Purchase Agreement.

On May 3, 2023, the Company sold 284,090 shares of common stock to Keystone under the Purchase Agreement at a purchase price of $0.18 per share, generating gross proceeds of $50,000.

Between May 4 and May 5, 2023, the Company sold a total of 626,911 shares of common stock to Keystone under the Purchase Agreement at a purchase price of $0.16 per share, generating total gross proceeds of $100,000.

As a result of these Dilutive Issuances (as defined in the Certificate of Designation for the Series I Preferred Stock and the related Warrants issued in the 2022 Rights Offering), the conversion price of the Series I Preferred Stock and the exercise price of the Warrants have been adjusted to $0.16 per share. Based on the adjusted conversion price, each share of the Series I Preferred Stock is convertible into 6,250 shares of common stock.

Letter of Intent for Asset Purchase Agreement

On April 26, 2023 the Company executed a Letter of Intent with Respect to Cardinal Milestone Payment (the "LOI") with Keystone. Pursuant to the LOI, the parties intend that, subject to the satisfaction of various conditions, Keystone would acquire a $10 million milestone payment which would be paid to the Company by Cardinal Health 414, LLC ("Cardinal Health") at such time as annual sales of Lymphoseek exceed $100 million in a fiscal year for a purchase price of $8 million. The right to receive the milestone payment will be backed by the Company's issuance of 10,000 shares of Series I convertible preferred stock ("Series I Stock") plus 5-year warrants with an exercise price of $0.50 per share. The Series I Stock will be forfeited upon payment of the milestone payment to Keystone. The conditions for closing include, among others, (i) the Company raising a minimum amount of new equity as agreed upon by the parties, and (ii) Mr. Scott converting all of his promissory notes into shares of Series I Stock and warrants.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to:

- the impact of the current conflict between Ukraine and Russia on our business, financial condition or prospects, including extreme volatility in the global capital markets making debt or equity financing more difficult to obtain, more costly or more dilutive, delays and disruptions of the global supply chains and the business activities of our suppliers, distributors, customers and other business partners;
- our history of operating losses and uncertainty of future profitability;
- our ability to successfully complete research and further development of our drug candidates;
- the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates, including delays and additional costs related to the current Russia-Ukraine conflict;
- our ability to successfully commercialize our drug candidates, including delays or disruptions related to the current Russia-Ukraine conflict;
- our ability to raise capital sufficient to fund our development programs, including unavailability of funds or delays in receiving funds as a result of the current Russia-Ukraine conflict;
- delays in receipt of anticipated proceeds from our capital funding transactions and other receivables;
- our dependence on royalties and grant revenue;
- our limited product line and distribution channels;
- advances in technologies and development of new competitive products;
- our ability to maintain effective control over financial reporting;
- the outcome of any pending litigation;
- our ability to comply or regain compliance with NYSE American continued listing standards; and
- other risk factors set forth in this report and detailed in our most recent Annual Report on Form 10-K and other Securities and Exchange Commission ("SEC") filings.

In addition, in this report, we use words such as "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," "project," and similar expressions to identify forward-looking statements.

We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

The Company

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

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. Other than Tc99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, none of the Company's drug product candidates have been approved for sale in any market.

We manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform, and (ii) therapeutic applications of our Manocept platform. See Note 15 to the consolidated financial statements for more information about our business segments.

In the near term, the Company intends to continue to develop our additional imaging product candidates into advanced clinical testing, as well as working to extend 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.

Technology and Product Candidates

Our primary development efforts over the last several years were focused on diagnostic products, including Tc99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States. Our more recent initiatives have been focused on diagnostic and therapeutic line extensions based on our Manocept platform.

As a brief overview of recent developments in the Company's diagnostics area (additional details in following sections), Navidea has completed the Phase 2b clinical trial (NAV3-31) evaluating imaging repeatability, reproducibility, and stability, as well as the capacity of Tc99m tilmanocept imaging to serve as an early predictor of treatment efficacy of anti-tumor necrosis factor alpha ("TNFα") therapy in patients with moderate to severe Rheumatoid Arthritis ("RA"). In addition, the Company has completed enrollment into a Phase 2b clinical trial (NAV3-35) designed to accrue hand and wrist planar and single photon emission computed tomography/computed tomography ("SPECT/CT") images from healthy subjects (with SPECT/CT imaging also done on a small group of RA patients) so that Navidea can complete a normative database in support of its RA imaging commercial product development. The Company's ongoing pivotal Phase 3 trial for RA (NAV3-33) is the next step in the development plan for indications in RA. The additional Phase 2b trial (NAV3-32) correlating Tc99m tilmanocept uptake in RA-involved joints with CD206 immunohistochemistry findings from synovial biopsies is actively recruiting. In addition, the investigator-initiated Phase 2 cardiovascular ("CV") study was completed at Massachusetts General Hospital and a manuscript has been submitted by the investigators. Results of this study provided to date have paralleled data in our earlier published article, and these data are supportive of Navidea's hypothesis that tilmanocept can provide marked signal to background in a host of CV disease applications.

Manocept Platform - Diagnostics and Therapeutics Background

Navidea's Manocept platform is predicated on the ability to specifically target the mannose receptor (CD206) expressed primarily on activated macrophages. This flexible and versatile platform serves as a molecular backbone for purpose-built targeted imaging molecules that may significantly impact patient care by providing enhanced diagnostic accuracy, clinical decision-making, and target-specific treatment. This CD206-targeted drug platform is applicable to a range of diagnostic modalities, including SPECT, positron emission tomography ("PET"), gamma-scanning and intra-operative and/or optical-fluorescence detection, as well as delivery of therapeutic compounds that target macrophages and their role in a variety of immune- and inflammation-involved diseases. The United States Food and Drug Administration ("FDA")-approved sentinel node/lymphatic mapping agent, Tc99m tilmanocept, is representative of the ability to successfully exploit this mechanism to develop powerful new products and to expand this technology into additional diagnostic and therapeutic applications.

Activated macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. Impairment of the macrophage-driven disease mechanisms is an area of increasing and proven focus in medicine. The number of people affected by all the inflammatory diseases combined is estimated at more than 40 million in the United States and up to 700 million worldwide, making macrophage-mediated diseases an area of remarkable clinical importance. There are many recognized disorders having macrophage involvement, including RA, atherosclerosis/vulnerable plaque/cardiovascular disease, nonalcoholic steatohepatitis ("NASH"), inflammatory bowel disease ("IBD"), systemic lupus erythematosus, cancer generally including Kaposi's sarcoma ("KS"), leishmaniasis, and others that span general clinical areas in cancer immunology, autoimmunity, infectious diseases, cardiology, central nervous system diseases, and inflammation. For the near term, we have selected target diseases that may, if successfully developed, benefit from this technology.

The Company has developed processes for producing the first four therapeutic Manocept immuno-construct series, the Manocept doxorubicin ("MAN-DOX") series, which is designed to specifically target and kill or modify activated CD206+ macrophages by delivering doxorubicin, a Manocept paclitaxel series ("MAN-PAC"), and a Manocept Bisphosphonate series ("MAN-BIS"). The MAN-PAC and MAD-BIS series are designed to modify CD206+ macrophages to make them more proinflammatory. The Company has also created a Manocept dexamethasone ("MAN-DEX") series, which is designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent, dexamethasone. We have expended significant efforts in recent years to improve chemical syntheses and to produce sufficient quantities of Manocept constructs representing all 4 series agents, along with the concomitant analytical standards, to provide material for current and planned preclinical animal studies and future clinical trials. Evaluation of representative examples of constructs from all four series have been successfully performed in human macrophage cell culture assays with MAN-DOX and MAN-PAC advancing to evaluations in various syngeneic mouse models of cancer.

Manocept Platform – Immuno-Diagnostics Clinical Data

Rheumatoid Arthritis

Two Tc99m tilmanocept dose escalation studies in RA have been completed. The first study was completed and included 18 subjects (nine with active disease and nine healthy subjects) dosed subcutaneously ("SC") with 50 and 200 µg/2mCi Tc99m tilmanocept (ClinicalTrials.gov NCT02683421). The results of this study were presented at five international meetings, including Biotechnology Innovation Organization, Society of Nuclear Medicine and Molecular Imaging ("SNMMI"), and The American College of Rheumatology ("ACR"). In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have completed a Phase 1/2 study involving intravenous ("IV") dosing of 39 subjects with IV-administered Tc99m tilmanocept (ClinicalTrials.gov NCT02865434). In conjunction with this study, we completed pharmacokinetic, pharmacodynamics and radiation dosimetry phases in human subjects as well. The majority of the costs of these studies were supported through a Small Business Innovation Research ("SBIR") grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1). Results of the Phase 1/2 study were presented at the June 2018 and June 2019 SNMMI meetings, the 2018 European League Against Rheumatism ("EULAR") meeting and the 2018 ACR meeting. A manuscript intended for peer reviewed publication is in preparation.

The Phase 1/2 study enrolled subjects with active, moderate-to-severe RA, and healthy controls. Results from the completed trial demonstrated that Tc99m tilmanocept is well-tolerated with no serious adverse events, adverse drug reactions, or drug-related adverse events observed. Additionally, static planar images revealed joint-specific Tc99m tilmanocept localization in RA subjects to disease-involved joints of the shoulders, knees, hands, and feet, but no joint-specific localization in healthy control subjects, revealing potentially significant immunodiagnostic information about CD206-expressing synovial macrophage involvement in RA. An optimal imaging time window post-Tc99m tilmanocept IV administration, as well as optimal dosing, were also determined.

In April 2019, the Company received feedback from the FDA regarding the Company's planned clinical studies to evaluate joint disease in patients with RA and monitor patient response to therapy. The Company's proposed RA studies were discussed with the FDA during an in-person meeting and through follow-up collaborative efforts. The FDA communicated that the first study, a Phase 2b trial, was aligned with expectations for the studies and that they would continue to work with Navidea as the Company progressed into the second Phase 2b trial correlating Tc99m tilmanocept uptake in RA-involved joints with CD206 immunohistochemistry findings from synovial biopsies and into the planned Phase 3 clinical trial.

In May 2019, we began enrolling patients into the first Phase 2b study, (NAV3-31), entitled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value ("TUV") on Tc99m Tilmanocept Planar Imaging" (ClinicalTrials.gov NCT03938636). This study, since completed, provided confirmatory support necessary to initiate Navidea's Phase 3 study program. In October 2019, the Company performed its first interim analysis of this trial, covering subjects enrolling into Arms 1 and 2. The results of this interim analysis were in line with the Company's hypotheses that Tc99m tilmanocept can provide robust, stable imaging in healthy subjects as well as in patients with active RA, and provide the fundamental information needed to keep moving forward into the Phase 3. A summary of these results was presented at the 2020 EULAR meeting. In May 2020, the Company announced the results of its second interim analysis, covering Arm 3 of the trial. This Arm mirrored the Phase 3 in design and provided information relevant for sample size calculation for the Phase 3 as well as support for the hypothesis that Tc99m tilmanocept imaging can provide an early indicator of treatment efficacy of anti-TNFα therapeutics. These interim results were presented at the 2020 ACR meeting. In June 2020, the Company announced full enrollment into this trial, with imaging events completed in each patient enrolled in Arm 3. A poster presentation based on the completed NAV3-31 study was presented at the 2022 ACR meeting. The Company also presented interim results of its NAV3-32 study at the 2022 ACR meeting.

In February 2021, the Company submitted its formal briefing book to the FDA, containing detailed analysis and discussion of the Company's then-ongoing Phase 2b study (NAV3-31) and prior studies in RA as well as the design and statistical analysis plan for the proposed Phase 3 for FDA comment. Following the feedback received from the FDA at the end of March 2021, the Company continued to work toward completing the analysis of the full NAV3-31 trial dataset and submitted the resultant briefing book containing the results of this analysis in preparation for the standard End-of-Phase 2 Type B meeting, which took place on September 1, 2021. The Company had a constructive meeting with the FDA and, based on the discussion in this meeting and follow-up communication, made agreed-upon modifications to the trial design for the Phase 3 study (NAV3-33). The Company submitted the modified protocol back to the FDA and initiated the study in December 2021. Following additional feedback from the FDA, the Company made modifications to several of the objectives. Enrollment into the Phase 3 study is ongoing. The pivotal Phase 3 study program will determine Tc99m tilmanocept's capability to serve as an early predictor of treatment response to anti-TNFα therapy in patients with RA. The current aim is for enrollment completion of the Phase 3 by end of 2023 with NDA submission targeted for late 2024 or early 2025.

Cardiovascular Disease

In collaboration with researchers at Massachusetts General Hospital, Navidea has completed two investigator-initiated clinical studies evaluating Tc99m tilmanocept's ability to enable imaging of atherosclerotic plaques. Results of these studies provide strong preliminary evidence of the potential of Tc99m tilmanocept to accumulate specifically in and enable imaging of non-calcified atherosclerotic plaques. Non-calcified atherosclerotic plaques include plaques with morphologies indicating a high risk of rupture. Rupture of such plaques causes myocardial infarctions (heart attacks) and a significant portion of ischemic strokes. The studies compared aortic Tc99m tilmanocept uptake imaged by SPECT/CT in clinically asymptomatic subjects with intermediate Framingham Risk Scores ("FRS") who were infected with Human Immunodeficiency Virus ("HIV") as compared to healthy, uninfected, FRS and age-matched subjects. Tc99m tilmanocept SPECT/CT images were compared to aortic images of the same subjects obtained by contrast enhanced coronary computed tomography angiography and/or [18F]NaF PET/CT.

A nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc99m tilmanocept product dosed SC was performed (ClinicalTrials.gov NCT02542371). The results of this study were presented at two major international meetings (Conference on Retroviruses and Opportunistic Infections and SNMMI, 2017) and published in early release in the *Journal of Infectious Diseases* in January 2017 (published in the circulated version, *Journal of Infectious Diseases* (2017) 215 (8): 1264-1269), confirming that the Tc99m tilmanocept product can both quantitatively and qualitatively target non-calcified plaque in the aortic arch of Acquired Immunodeficiency Syndrome ("AIDS") patients (supported by NIH/NHLBI Grant 1 R43 HL127846-01). This study was later expanded to include up to 31 participants, achieved full enrollment, and a publication has resulted in the *Journal of Infectious Diseases* (2022) Nov 11; 226(10):1823-1833.

A second Phase 1/2 investigator-initiated study in cooperation with Massachusetts General Hospital in subjects with HIV was initiated that expanded the original study in both the scope of the drug administration as well as the diagnostic assessment of the subjects. This study enrolled both AIDS subjects and healthy controls in imaging non-calcified plaque using IV and SC-administered Tc99m tilmanocept and will expand the initial investigation to the assessment of aortic plaque as well as carotid and coronary arteries. Initial analysis suggested that the SC route of administration led to superior signal-to-background in areas of non-calcified plaque. These results are being further assessed.

Navidea was also awarded a $225,000 phase 1 Small Business Technology Transfer grant (1R41HL147640-01A1) entitled *Gallium 68 Tilmanocept for PET Imaging of Atherosclerosis Plaques*. This grant supported a research collaboration between Navidea and Dr. Suzanne Lapi of the University of Alabama Birmingham ("UAB") evaluating a mouse model of atherosclerosis. This work had as its aim the evaluation of [68]gallium tilmanocept and various next generation imaging agents for visualizing plaques. Activities began in the fourth quarter of 2019. In follow on experiments related to the work done on atherosclerosis, UAB and Navidea collaborated on other imaging experiments that evaluated next generation Manocept imaging agents and other constructs designed to block off target localization to the liver to enhance visualization of tumors using the CT26 mouse model of cancer. These efforts were successful and resulted in new patent applications and, on March 6, 2023, in a publication in the journal Molecular Imaging and Biology.

Kaposi's Sarcoma

We initiated and completed a study of KS in 2015 (ClinicalTrials.gov NCT022201420) and received additional funding from the National Institutes of Health ("NIH") in 2016 to continue diagnostic studies in this disease. The new support not only continues the imaging of the cutaneous form of this disease but expands this to imaging of visceral disease via IV administration of Tc99m tilmanocept (NIH/NCI 1 R44 CA192859-01A1; ClinicalTrials.gov NCT03157167). This now-escalated study includes a pathology/biopsy component as well as an imaging component to determine pathology concordance with image assessment. We received Institutional Review Board approval of the clinical protocol and initiated a Phase 1/2 clinical study in KS in 2017. This trial has completed enrollment and imaging, with final data analysis and clinical study report preparation well underway.

Tuberculosis ("TB")

In April 2019, the Company announced that Professor Mike Sathekge, MBChB, M. Med (Nuclear Medicine), PhD, Professor and Head of the Department of Nuclear Medicine in the Faculty of Health Sciences at the University of Pretoria/Steve Biko Academic Hospital, planned to initiate a comparative study evaluating the use of tilmanocept in patients with TB. The purpose of this ongoing study is to explore using 68Ga tilmanocept as an aid in TB patient management while contributing to the better understanding of the biology of TB granulomas. CD206+ macrophages constitute one of the most abundant cell types in TB granulomas. Therefore, a molecular probe such as 68Ga-labeled tilmanocept targeting mannose receptor CD206 expressed on macrophages holds great promise not only in understanding the biology of TB granulomas, but may also support future development of a tilmanocept-like drug delivery vehicle for delivering therapeutic interventions to TB granulomas. Navidea has provided tilmanocept for use in this study, and several subjects have been injected and imaged to date. Successful completion of this study could support an extended claim of 68Ga-tilmanocept.

Biomarker Application and Qualification

In November 2017, the Company commenced the qualification of the biomarker CD206 with the FDA Biomarker Section of The Center for Drug Evaluation and Research ("CDER"). As per FDA protocol, Navidea submitted a draft letter of intent ("LOI") to CDER prior to the November 2017 meeting. According to the CDER directive, "the Biomarker Qualification Program was established to support the CDER's work with external stakeholders to develop biomarkers that aid in the drug development process. Through the FDA's Biomarker Qualification Program, an entity may request regulatory qualification of a biomarker for a particular context of use ("COU") in drug development." Following the meeting with the FDA, and because of Navidea's data sets and the general external publication database, Navidea, in conjunction with FDA, is now reviewing the LOI with the FDA's recommended consultants. Navidea has revised the LOI draft strategy in order to expedite the application process. In March 2018, Navidea had a follow-up meeting with the FDA's assigned strategist, during which the potential to further narrow the LOI elements was reviewed. Navidea is continuing the process of finalizing the COU LOI and will be providing the background data sets for qualification review with the FDA/CDER. Additional meetings have taken place and the pursuit of this qualification is ongoing. A pivotal element of this will be the data obtained from the NAV3-32 clinical trial.

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

The Company has been developing Manocept platform drug delivery constructs that carry various payloads. Chemical synthesis techniques have advanced considerably, resulting in more robust and reproducible synthesis protocols that provide products with chemical attributes indicative of enhanced in vivo activity. Particularly significant results included improved processes for adding mannose moieties to the amine-terminated linkers on the dextran backbone and significant advances in the design and functionality of the degradable linkers to which drug payloads are attached. These advances in chemical methods are the subject matter of several patent applications currently under review by the USPTO. Experiments utilizing human macrophage assays show that at treatment doses of MAN-DOX, MAN-PAC, and MAN-BIS below what is required to kill macrophages, all three construct series dramatically alter the immunological behavior of macrophages, making them more proinflammatory. Results indicate that MAN-BIS and MAN-PAC constructs are more active at altering macrophage behavior towards a proinflammatory status than MAN-DOX. In syngeneic mouse tumor experiments, the MAN-DOX and MAN-PAC constructs significantly synergized the activity of another anticancer therapy producing anti-tumor activity that was greater than either treatment alone. Consistent with the macrophage cell assay results, MAN-PAC was more active than MAN-DOX in synergizing the activity of the other anti-cancer therapy. Similar studies evaluating the MAD-BIS constructs in syngeneic mouse tumor models are pending. Results from the completed studies have been presented at the New York Academy of Sciences Frontiers in Cancer Immunotherapy 2021 (MAN-DOX, May 14, 2021), at the Tumor Myeloid-Directed Therapies Summit (MAN-BIS, June 2022), and at the Society for Immunotherapy of Cancer (SITC) (MAN-PAC, Nov. 10, 2022). Work involving a second generation Manocept dexamethasone-carrying construct (MAN-DEX) has progressed to evaluations in human macrophage culture assays, showing that the MAN-DEX suppressed the proinflammatory behavior of human macrophages as expected.

Kaposi's Sarcoma

The novel MAN-DOX class constructs are designed to specifically deliver doxorubicin, a chemotoxin, which can kill KS tumor cells and their tumor-associated macrophages, potentially altering the course of cancer. We received additional funding to continue therapeutic studies in this disease with the goal of completing an investigational new drug ("IND") submission for a Manocept construct (MAN-DOX class of compounds) consisting of tilmanocept linked to doxorubicin for the treatment of KS. Efforts supported by this grant (NIH/NCI 1 R44 CA206788-01) are now complete. The results greatly advanced our knowhow for robustly and reproducibly synthesizing MAN-DOX and related constructs carrying other payloads. The grant-supported efforts were presented at the New York Academy of Sciences Frontiers in Cancer Immunotherapy 2021.

Other Immunotherapeutic Applications

The Company continues to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform, including ongoing studies in KS, RA and infectious diseases such as leishmaniasis. In collaboration with investigators at the NIH, four experiments in various mouse models of leishmaniasis have been completed evaluating several of Navidea's Manocept constructs for therapeutic efficacy. Promising results were observed that are currently being followed up upon. 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.

Outlook

Our operating expenses in recent years have been focused primarily on support of both diagnostic and therapeutic applications of our Manocept platform, and Tc99m tilmanocept. We incurred approximately $1.3 million and $1.2 million in total on R&D activities during the three-month periods ended March 31, 2023 and 2022, respectively. Of the total amounts we spent on R&D during those periods, excluding costs related to our internal R&D 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:

	Three Months Ended March 31,	
Development Program	**2023**	**2022**
Manocept Platform – Diagnostics	$ 867,593	$ 364,547
Manocept Platform – Therapeutics	96,900	179,367
Tc99m Tilmanocept	9,921	1,648

We expect to continue the advancement of our efforts with our Manocept platform during the remainder of 2023. We currently expect our total R&D expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be lower in 2023 than in 2022.

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 European Union ("EU") and India. We anticipate that we will incur costs to support our product, regulatory, manufacturing and commercial activities related to the sale of Tc99m tilmanocept in the EU and India, as well as related to the potential marketing registration and sale of Tc99m tilmanocept in markets other than the EU and India. There can be no assurance that Tc99m tilmanocept will achieve regulatory approval in any market other than the EU and India, or if approved in those markets, that it will achieve market acceptance in the EU, India or any other market.

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. Similarly, Tc99m tilmanocept has been approved by the relevant regulatory agencies in the UK, India and Australia. We anticipate that we will incur costs to support our product, regulatory, manufacturing and commercial activities related to the sale of Tc99m tilmanocept in the EU, UK, India and Australia, as well as related to the potential marketing registration and sale of Tc99m tilmanocept in markets other than the EU, UK, India and Australia. There can be no assurance that Tc99m tilmanocept will achieve regulatory approval in any market other than the EU, UK, India and Australia, or if approved in those markets, that it will achieve market acceptance in those or any other markets.

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

Results of Operations

Our pharmaceutical products and product candidates are not yet generating significant commercial revenue and our operating variances focus on our product development programs and the supporting general and administrative expenses.

Three Months Ended March 31, 2023 and 2022

License Revenue. No license revenue was recorded during the first quarter of 2023 or 2022.

Grant and Other Revenue. No grant or other revenue was recognized during the first quarter of 2023 or 2022.

Research and Development Expenses. R&D expenses increased $98,000, or 8%, to approximately $1.3 million during the first quarter of 2023 from $1.2 million during the same period in 2022. The increase was primarily due to net increases in drug project expenses related to (i) increased Manocept diagnostic development costs of $503,000 including increased manufacturing-related activities and increased clinical trial costs; and (ii) increased Tc99m tilmanocept development costs of $8,000, primarily European regulatory consulting expenses; offset by (iii) decreased Manocept therapeutic development costs of $82,000 including decreased preclinical and clinical development costs and decreased manufacturing-related activities. The net increase in R&D expenses also included increased regulatory consulting expenses of $30,000 offset by decreased employee compensation including fringe benefits and incentive-based awards of $334,000, decreased recruiting fees of $17,000 and decreased general office expenses of $10,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $655,000, or 36%, to approximately $1.2 million during the first quarter of 2023 from $1.8 million during the same period in 2022. The decrease was primarily due to decreased legal and professional services of $501,000, decreased employee compensation including fringe benefits and incentive-based awards of $62,000, decreased losses on the abandonment of certain intellectual property of $47,000 and decreased director fees of $45,000 related to decreased board compensation rates.

Other Income (Expense). Other income, net, was $946,000 during the first quarter of 2023 compared to other expense, net, of $8,000 during the same period in 2022. During the first quarter of 2023, we recognized a gain on amendment of contracts of $1.2 million resulting from an amendment to our license agreement with UCSD for the exclusive world-wide rights to all diagnostic and therapeutic uses of tilmanocept (other than Tc99m tilmanocept used in lymphatic mapping). The amendment released the Company from any and all obligations related to certain diligence requirements as defined in the license agreement. During the first quarters of 2023 and 2022, we recognized interest expense of $263,000 and $4,000, respectively. The increase was primarily due to increases in interest expenses related to the Bridge Note of $142,000 and the CRG judgement of $115,000.

Liquidity and Capital Resources

Cash and cash equivalents decreased to $34,000 as of March 31, 2023 from $2.0 million as of December 31, 2022. The net decrease was primarily due to cash used to fund our operations of $1.7 million, payments on notes payable of $201,000, patent and trademark costs of $24,000 and purchases of equipment of $15,000.

Operating Activities. Cash used in operations was $1.7 million during the first quarter of 2023 compared to $2.6 million used during the same period in 2022.

Receivables increased to $31,000 as of March 31, 2023 from less than $1,000 as of December 31, 2022, primarily due to the expected refund of unused research sponsorship funds related to preclinical study.

Inventory, net increased to $461,000 as of March 31, 2023 from $427,000 as of December 31, 2022, primarily due to the manufacture of two batches of finished goods that were in process as of March 31, 2023.

Prepaid expenses and other current assets decreased to $672,000 as of March 31, 2023 from $780,000 as of December 31, 2022, primarily due to normal amortization of prepaid insurance of $178,000, which was offset by increased deferred stock offering and deferred debt issuance costs of $75,000.

Accounts payable increased to $3.2 million as of March 31, 2023 from $2.1 million as of December 31, 2022, primarily due to net increased payables due for clinical development activities, legal and professional services, and deferred board of director fees.

Accrued liabilities and other current liabilities decreased to $4.9 million as of March 31, 2023 from $6.5 million as of December 31, 2022. Net decreased accruals related to clinical development activities, including the reversal of accruals resulting from the UCSD license amendment, incentive-based compensation, employee benefits, and the separation of our former Chief Executive Officer and Chief Medical Officer were offset by net increased accruals related to legal and professional services. Our payable and accrual balances will continue to fluctuate but will likely decrease overall when the Company secures additional financing.

Investing Activities. Investing activities used $39,000 during the first quarter of 2023 compared to $118,000 used during the same period in 2022. Patent and trademark costs used $24,000 and purchases of property and equipment used $15,000 during the first quarter of 2023. Patent and trademark costs used $76,000 and purchases of property and equipment used $42,000 during the first quarter of 2022.

Financing Activities. Financing activities used $201,000 during the first quarter of 2023 compared to $339,000 million used during the same period in 2022. The $201,000 used by financing activities in the first quarter of 2023 consisted of principal payments on financed insurance premiums of $201,000. The $339,000 used by financing activities in the first quarter of 2022 consisted of principal payments on financed insurance premiums of $339,000.

CRG Litigation

See Notes 2 and 10 to the accompanying condensed consolidated financial statements.

Goldberg Agreement and Litigation

See Notes 2 and 10 to the accompanying condensed consolidated financial statements.

Summary

Our future liquidity and capital requirements will depend on a number of factors, including the ability to procure required financial resources, the ability of our distribution partners to achieve market acceptance of our products, our ability to complete the development and commercialization of new products, our ability to obtain milestone or development funds from potential development and distribution partners, regulatory actions by the FDA and international regulatory bodies, the outcome of any pending litigation, and intellectual property protection.

We plan to focus our resources during the remainder of 2023 on development of products based on the Manocept platform. Although management believes that it will be able to achieve this objective, it is subject to a number of variables beyond our control, including the nature and timing of any partnering opportunities, the ability to modify contractual commitments made in connection with these programs, and the timing and expense associated with suspension or alteration of clinical trials, and consequently it is likely we will need to seek additional financing in order to support our planned development programs.

On April 25, 2023, Mr. Scott agreed to make a second loan to the Company in the principal amount of up to $300,000 under the terms of the 2023 Bridge Note, of which $225,000 and $75,000 were funded on April 26, 2023 and May 9, 2023, respectively. The Company has agreed to pay a non-refundable fee of $15,000 due to Mr. Scott at maturity on June 26, 2023. The Company's obligations under the 2023 Bridge Note are secured by a first priority security interest in all of the Company's assets and personal property pursuant to the Security Agreement dated April 10, 2022, as amended on April 25, 2023 in favor of Mr. Scott.

On April 26, 2023, the Company entered into a Purchase Agreement with Keystone under which the Company may sell from time to time at its sole discretion (subject to certain limitations and conditions) up to $2,750,000 of shares of the Company's common stock, Under the Purchase Agreement, the Company agreed to issue to Keystone 400,000 shares of Common Stock as consideration for its commitment to purchase shares under the Purchase Agreement, with 200,000 shares (based on the closing stock price of $0.25 as April 25, 2023) being delivered on the date of the Purchase Agreement and the remaining 200,000 shares (based on the closing stock price of $0.25 as April 25, 2023) to be delivered upon the Company raising a minimum of $2,750,000 under the Purchase Agreement or any other source. On May 3, 2023 the Company sold 284,090 shares of common stock to Keystone under the Purchase Agreement at a purchase price of $0.18 per share, generating gross proceeds of $50,000. Between May 4 and May 5, 2023, the Company sold a total of 626,911 shares of common stock to Keystone under the Purchase Agreement at a purchase price of $0.16 per share, generating total gross proceeds of $100,000. The shares that may be issued and sold under the Purchase Agreement are registered under the Company's shelf registration statement on Form S-3 (File No. 333-252847) and the related prospectus supplement dated April 27, 2023.

We will continue to evaluate our timelines, strategic needs, and balance sheet requirements. If we attempt to raise additional capital through debt, royalty, equity or otherwise, we may not be successful in doing so on terms acceptable to the Company, if at all. We may not be able to gain access and/or be able to secure new sources of funding, identify new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future.

The Company is currently engaged in litigation with Dr. Goldberg and CRG. As of March 31, 2023, the Company has accrued approximately $3.5 million of legal fees and interest pursuant to the CRG judgment. The amount of ultimate liability, if any, with respect to the Goldberg litigation is unknown.

The current conflict between Ukraine and Russia has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties who operate in Europe on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any debt or equity financing more difficult to obtain, more costly or more dilutive. The Company will continue to evaluate the impact that the Russia-Ukraine conflict could have on the operations, financial position, and the results of operations and cash flows during fiscal year 2023 and beyond.

The Company has experienced recurring net losses and has used significant cash to fund its operations. The Company has considerable discretion over the extent of development project expenditures and has the ability to curtail the related cash flows as needed. The Company also continues working to establish new sources of funding, including potential equity or debt investments, collaborations and additional grant funding that can augment the balance sheet. However, the Company may be unable to raise sufficient capital when it needs it or on favorable terms. Based on our current working capital and our projected cash burn, management believes that there is substantial doubt about the Company's ability to continue as a going concern for a period of one year from the filing of this Quarterly Report on Form 10-Q. No adjustments have been made to the accompanying condensed consolidated financial statements as a result of this uncertainty. See Note 2 to the accompanying condensed consolidated financial statements.

As of March 31, 2023, we had no off-balance sheet arrangements.

Recent Accounting Standards

See Note 1(h) to the accompanying condensed consolidated financial statements.

Critical Accounting Policies

We base our management's discussion and analysis of financial condition and results of operations, as well as disclosures included elsewhere in this Quarterly Report on Form 10-Q, upon our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We describe our significant accounting policies in the notes to the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 27, 2023 ("2022 Form 10-K"). We include within these policies our "critical accounting policies." Critical accounting policies are those policies that are most important to the preparation of our consolidated financial statements and require management's most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Changes in estimates and assumptions based upon actual results may have a material impact on our results of operations and/or financial condition.

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

We also earn revenue from product sales to end customers, primarily in Europe. Revenue from product sales is generally recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which occurs upon either shipment of the product or arrival at its destination, depending upon the shipping terms of the transaction. 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.

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

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

Debt. We evaluate newly-issued debt instruments in accordance with Accounting Standards Codification ("ASC") 470, *Debt*.

Preferred Stock. We evaluate newly-issued preferred stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*, ASC 815, *Derivatives and Hedging*, ASC 470, *Debt* and Accounting Series Release ("ASR") 268, *Presentation in Financial Statements of* "*Redeemable Preferred Stocks*."

Preferred Stock Issued with Warrants. We evaluate preferred stock issued with warrants in accordance with ASC 480, *Distinguishing Liabilities from Equity*, ASC 815, *Derivatives and Hedging* and ASR 268, *Presentation in Financial Statements of* "*Redeemable Preferred Stocks*."

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.

Critical Accounting Estimates

There have been no material changes to the Company's critical accounting estimates as previously reported in the Company's 2022 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to smaller reporting companies.

Item 4. 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, 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 March 31, 2023. Based on that evaluation, our principal executive officer and principal financial and accounting officer 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 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.

Changes in Control Over Financial Reporting

During the quarter ended March 31, 2023, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

See Note 10 to the accompanying condensed consolidated financial statements.

Item 1A. Risk Factors

There have been no material changes to the Company's risk factors as previously reported in the Company's 2022 Form 10-K.

Item 6. Exhibits

31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
32.2	Certification of Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
101.INS	Inline XBRL Instance Document (the Instance Document does not appear in the Interactive Data File because it is XBRL) (1)
101.SCH	Inline XBRL Taxonomy Extension Schema Document (1)
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (1)
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (1)
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (1)
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (1)
104	Cover page Interactive Data File (formatted as Inline XBRL and combined in Exhibit 101.1)

* Filed herewith.

** Furnished herewith.

(1) These interactive data files shall not be deemed filed for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under those sections.

Items 2, 3, 4 and 5 are not applicable and have been omitted.

SIGNATURES

Pursuant to the requirements 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.

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
May 11, 2023

By: */s/ John K. Scott, Jr.*

John K. Scott, Jr.
Vice Chairman of the Board of Directors
(Principal Executive Officer)

By: */s/ Joseph W. Meyer*

Joseph W. Meyer
Director, Finance and Accounting
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, John K. Scott, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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(s) 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(s) 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.

May 11, 2023

/s/ John K. Scott, Jr.
John K. Scott, Jr.
Vice Chairman of the Board of Directors
(Principal Executive Officer)

Exhibit 31.2

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

I, Joseph W. Meyer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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(s) 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(s) 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.

May 11, 2023

/s/ Joseph W. Meyer
Joseph W. Meyer
Director, Finance and Accounting
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Navidea Biopharmaceuticals, Inc. (the "Company") for the quarter ended March 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), the undersigned, John K. Scott, Jr., Vice Chairman of the Board of Directors (Principal Executive Officer) of the Company, hereby certifies as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 11, 2023

/s/ John K. Scott, Jr.
John K. Scott, Jr.
Vice Chairman of the Board of Directors
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Navidea Biopharmaceuticals, Inc. (the "Company") for the quarter ended March 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), the undersigned, Joseph W. Meyer, Director of Finance and Accounting (Principal Financial and Accounting Officer) of the Company, hereby certifies as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 11, 2023

/s/ Joseph W. Meyer
Joseph W. Meyer
Director, Finance and Accounting
(Principal Financial and Accounting Officer)