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, 2022

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:30,359,792 shares of common stock, par value $.001 per share (as of the close of business on May 9, 2022).

NAVIDEA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,217,114	$ 4,230,865
Receivables	115,845	92,992
Inventory	322,992	151,155
Prepaid expenses and other	667,439	908,273
Total current assets	2,323,390	5,383,285
Property and equipment	908,322	866,306
Less accumulated depreciation and amortization	756,385	745,816
Property and equipment, net	151,937	120,490
Right-of-use lease assets	448,940	448,940
Less accumulated amortization	351,078	320,725
Right-of-use lease assets, net	97,862	128,215
License agreements, patents and trademarks	981,825	953,424
Less accumulated amortization	180,081	167,773
License agreements, patents and trademarks, net	801,744	785,651
Other assets	227,192	227,192
Total assets	$ 3,602,125	$ 6,644,833
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 1,564,933	$ 1,421,317
Accrued liabilities and other	3,023,221	3,149,340
Notes payable	113,974	453,427
Lease liabilities, current	198,140	275,718
Total current liabilities	4,900,268	5,299,802
Lease liabilities, net of current portion	11,299	20,288
Deferred revenue	800,000	700,000
Total liabilities	5,711,567	6,020,090
Commitments and contingencies (See Note 10)		
Stockholders' (deficit) equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding as of March 31, 2022 and December 31, 2021	—	—
Series D preferred stock; $.001 par value, 150,000 shares authorized; 22,077 shares issued and outstanding as of March 31, 2022 and December 31, 2021	22	22
Series E preferred stock; $.001 par value, 50,000 shares authorized; 50,000 shares issued and outstanding as of March 31, 2022 and December 31, 2021	50	50
Common stock; $.001 par value, 300,000,000 shares authorized; 30,357,292 and 30,279,922 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	221,354	221,277
Additional paid-in capital	371,151,466	370,459,705
Accumulated deficit	(373,774,852)	(370,787,610)
Total stockholders' deficit	(2,401,960)	(106,556)
Noncontrolling interest	292,518	731,299
Total Navidea stockholders' (deficit) equity	(2,109,442)	624,743
Total liabilities and stockholders' (deficit) equity	$ 3,602,125	$ 6,644,833

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
License revenue	$ —	$ 22,486
Grant and other revenue	—	101,251
Total revenue	—	123,737
Cost of revenue	—	—
Gross profit	—	123,737
Operating expenses:		
Research and development	1,169,254	1,222,754
Selling, general and administrative	1,810,030	2,230,745
Total operating expenses	2,979,284	3,453,499
Loss from operations	(2,979,284)	(3,329,762)
Other (expense) income:		
Interest expense, net	(3,662)	(2,875)
Gain on extinguishment of debt	—	366,000
Other, net	(4,299)	(255)
Total other (expense) income, net	(7,961)	362,870
Net loss	(2,987,245)	(2,966,892)
Loss attributable to noncontrolling interest	3	2
Loss attributable to common stockholders	$ (2,987,242)	$ (2,966,890)
Loss attributable to common stockholders per common share (basic and diluted)	$ (0.10)	$ (0.11)
Weighted average shares outstanding	30,207,746	28,066,296

See accompanying notes to condensed consolidated financial statements.

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

For the Three Months Ended March 31, 2022

	Preferred Stock		Common Stock Issued					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Non-controlling Interest	Total
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)

For the Three Months Ended March 31, 2021

	Preferred Stock		Preferred Stock Subscribed			Common Stock Issued		Common Stock Subscribed						
	Shares	Amount	Shares	Amount	Preferred Stock Subscriptions Receivable	Shares	Amount	Shares	Amount	Common Stock Subscriptions Receivable	Additional Paid-In Capital	Accumulated Deficit	Non-controlling Interest	Total
Balance, January 1, 2021	-	$ -	132,250	$ 132	$ (10,300,000)	27,149,691	$ 218,146	995,000	$ 995	$ (4,975,000)	$ 375,428,014	$ (359,056,683)	$ 731,303	$ 2,046,907
Issued restricted stock	-	-	-	-	-	12,500	13	-	-	-	-	-	-	13
Issued stock to 401(k) plan	-	-	-	-	-	30,018	30	-	-	-	76,816	-	-	76,846
Issued Series D Preferred Stock	31,750	32	(31,750)	(31)	250,000	-	-	-	-	-	-	-	-	250,001
Issued stock upon conversion of Series D Preferred Stock	(31,750)	(32)	-	-	-	1,513,978	1,514	-	-	-	(1,482)	-	-	-
Series D Preferred Stock subscribed	-	-	-	-	500,000	-	-	-	-	-	-	-	-	500,000
Issued Series E Preferred Stock, net of issuance costs	50,000	50	-	-	-	-	-	-	-	-	4,980,659	-	-	4,980,709
Stock compensation expense	-	-	-	-	-	-	-	-	-	-	121,298	-	-	121,298
Net loss	-	-	-	-	-	-	-	-	-	-	-	(2,966,890)	(2)	(2,966,892)
Balance, March 31, 2021	50,000	$ 50	100,500	$ 101	$ (9,550,000)	28,706,187	$ 219,703	995,000	$ 995	$ (4,975,000)	$ 380,605,305	$ (362,023,573)	$ 731,301	$ 5,008,882

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,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (2,987,245)	$ (2,966,892)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	22,878	17,748
Non-cash lease expense	30,354	30,378
Loss on abandonment of patent applications	47,774	—
Stock compensation expense	184,850	121,298
Gain on extinguishment of debt	—	(366,000)
Value of stock issued to 401(k) plan for employer matching contributions	44,720	76,846
Value of stock issued in payment of employee bonuses	16,965	—
Value of stock issued in payment of director fees	6,525	—
Changes in operating assets and liabilities:		
Receivables	(22,852)	(21,414)
Inventory	(171,837)	3,556
Prepaid expenses and other assets	240,832	129,970
Accounts payable	143,616	72,403
Accrued and other liabilities	(149,083)	(106,135)
Lease liabilities	(86,567)	(77,256)
Deferred revenue	122,964	22,964
Net cash used in operating activities	(2,556,106)	(3,062,534)
Cash flows from investing activities:		
Payments for purchases of equipment	(42,017)	—
Patent and trademark costs	(76,175)	(67,472)
Net cash used in investing activities	(118,192)	(67,472)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, including stock subscriptions receivable	—	8,175,000
Payment of preferred stock issuance costs	—	(19,290)
Proceeds from issuance of common stock	—	13
Principal payments on notes payable	(339,453)	(188,893)
Net cash (used in) provided by financing activities	(339,453)	7,966,830
Net (decrease) increase in cash and cash equivalents	(3,013,751)	4,836,824
Cash and cash equivalents, beginning of period	4,230,865	2,670,495
Cash and cash equivalents, end of period	$ 1,217,114	$ 7,507,319

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, 2022 and for the three-month periods ended March 31, 2022 and 2021 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, 2022 and the results for the interim periods are not necessarily indicative of results to be expected for the year. The consolidated financial statements should be read in conjunction with Navidea's audited consolidated financial statements for the year ended December 31, 2021, which were included as part of our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 28, 2022 ("2021 Form 10-K").

Our 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. Revenue Recognition: We generate revenue from a grant to support one of 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 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.

c. 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.

d. 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.

e. 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, 2022 and 2021, we capitalized patent and trademark costs of $76,175 and $67,472, respectively. During the three-month periods ended March 31, 2022 and 2021, we abandoned patent applications with previously-capitalized patent costs of $47,774 and $0, respectively.

f. Leases: All of our leases are operating leases and are included in right-of-use lease assets, current lease liabilities and noncurrent lease liabilities on our consolidated balance sheets. These assets and liabilities are recognized at the commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates or implicit rates, when readily determinable. 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 consolidated balance sheets. Lease expense for operating leases is recognized on a straight-line basis over the lease term. Lease expense is included in selling, general and administrative expenses on our consolidated statements of operations. See Note 9.

g. 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. and our former President and Chief Executive Officer, Dr. Michael Goldberg. See Note 10.

h. Recently Adopted Accounting Standards: In May 2021, the Financial Accounting Standards Board ("FASB") Issued Accounting Standards Update ("ASU") No. 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* ASU 2021-04 was issued to clarify and reduce diversity in an issuer's accounting for modifications or exchange of freestanding equity-classified written call options (for example, warrants) that remain equity-classified after modification or exchange. ASU 2021-04 requires that an entity treat a modification or exchange of a freestanding equity-classified written call option that remains equity-classified after modification or exchange be treated as an exchange of the original instrument for a new instrument. ASU 2021-04 also clarifies how an entity should measure and recognize the effect of a modification or exchange of a freestanding equity-classified written call option that remains equity-classified after modification or exchange. ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, and should be implemented prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including in an interim period. The adoption of ASU 2021-04 did not have a material impact on our consolidated financial statements.

In November 2021, the FASB issued ASU No. 2021-10, *Disclosures by Business Entities about Government Assistance*. ASU 2021-10 was issued to increase the transparency of government assistance. ASU 2021-10 requires that entities make certain annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The required disclosures include: (1) information about the nature of the transactions and the related accounting policy used to account for the transactions; (2) the line items on the balance sheet and income statement that are affected by the transactions, and the amounts applicable to each financial statement line item; and (3) significant terms and conditions of the transactions, including commitments and contingencies. The amendments in ASU 2021-10 are effective for all entities within their scope for financial statements issued for annual periods beginning after December 15, 2021. Early application of the amendments is permitted. An entity should apply the amendments in ASU 2021-10 either (1) prospectively to all transactions within the scope of the amendments that are reflected in financial statements at the date of initial application and new transactions that are entered into after the date of initial application or (2) retrospectively to those transactions. The adoption of ASU 2021-10 did not have an impact on our consolidated financial statements, however we do expect to make the additional annual disclosures required by the update.

2. Liquidity

As disclosed in the notes to the consolidated financial statements included in the Company's 2021 Form 10-K, the Company has been engaged in litigation with Platinum-Montaur Life Sciences LLC ("Platinum-Montaur"), an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P., Platinum Partners Capital Opportunity Fund, Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, "Platinum"). In addition, the Company is engaged in ongoing litigation with our former President and Chief Executive Officer, Dr. Michael Goldberg. The Company has also been engaged in ongoing litigation with Capital Royalty Partners II L.P. ("CRG"). See Note 10.

On April 10, 2022, the Company entered into a Stock Exchange and Loan Agreement (the "Purchase Agreement") with John K. Scott, Jr., the current Vice Chairman of our Board of Directors, 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. The outstanding balance of the loan, which is evidenced by a Secured Term Note (the "Bridge Note"), will bear 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 Bridge Note is due and payable on the second anniversary of the Purchase Agreement. The Company's obligations under the 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. See Note 16.

We do not believe there has been a significant impact to the Company's clinical development and regulatory timelines resulting from the ongoing COVID-19 global pandemic. However, the COVID-19 outbreak delayed enrollment in our NAV3-32 clinical study in the United Kingdom due to national COVID-19-related shutdowns. In addition, the regulatory approval process in India was delayed by the impact of COVID-19 in that country.

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 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 investments, 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

Navidea is focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. We manage our business based ontwo 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 India, Europe and Australia.

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

Up-front and milestone payments received related to our license and distribution agreements in India and China are deferred untilTc99m 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 ofthird 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 havenot yet begun in India or China, therefore there is currently no basis for estimating whether, to what degree, or the rate at which the product will be accepted and utilized in these markets. Similarly, we currently have no basis for estimating whether sales-based milestones will ever be achieved. Accordingly, the Company recognizes revenue from royalties when the related sales occur and from sales-based milestones when they are achieved.

The Company also has an agreement in place to provide Meilleur Technologies, Inc. ("Meilleur"), a wholly-owned subsidiary of Cerveau Technologies, Inc. ("Cerveau"), worldwide rights to conduct research using NAV4694, as well as an exclusive license for the development and commercialization ofNAV4694 in Australia, Canada, China, and Singapore. Meilleur also has an option to commercialize worldwide.

The sublicense of NAV4694 to Meilleur provides for payments to Navidea including up-front payments, milestones, an option for worldwide commercial rights, royalties on net sales, and reimbursement for product development assistance during the initial transition period. In accordance with Accounting Standards Codification No. 606, *Revenue from Contracts with Customers* ("ASC 606"), the upfront payments were recognized upon contract inception, and reimbursement for product development assistance will be recognized on a monthly basis. Should some or all of the variable consideration from milestones, the option and royalties meet the requirements of the revenue recognition standard to be included in the transaction price, those amounts will be recognized as revenue in future periods.

Up-front fees, milestones and royalties are generally non-refundable. Therefore, the Company doesnot 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 endedMarch 31, 2022 and 2021, the Company recognized revenue from contracts with customers of $0 and $22,486, respectively. During the three-month periods endedMarch 31, 2022 and 2021, 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 thethree-month periods endedMarch 31, 2022 and 2021.

	Three Months Ended March 31,	
	2022	**2021**
License revenue:		
Tc99m tilmanocept - Europe	$ —	$ 22,486

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 turnmay 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 Europe, 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 andmay 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. Similarly, NAV4694 has not yet been approved for sale in any market, thus the timing of any revenue related to that product will be dependent on the regulatory pathways and timelines in each market in which Meilleur seeks regulatory approval.

Through March 31, 2022, the Company has not capitalized any contract-related costs as contract assets.

The following table summarizes the changes in contract liabilities, the current portion of which is included in accrued liabilities and other in the consolidated balance sheets, during the three-month periods ended March 31, 2022 and 2021.

	Three Months Ended March 31,	
	2022	2021
Total deferred revenue, beginning of period	$ 700,000	$ 700,000
Deferred revenue related to milestones achieved	100,000	—
Total deferred revenue, end of period	$ 800,000	$ 700,000

The Company had license revenue receivable of $100,000 and $1,021 outstanding as of March 31, 2022 and December 31, 2021, respectively.

In addition to revenue from contracts from customers, we also generate revenue from National Institutes of Health ("NIH") grants to support various product development initiatives. The revenue recognition standard applies to revenue from contracts with customers. A customer is defined as a party that has contracted with an entity to obtain goods or services that are an output of the entity's ongoing major or central operations in exchange for consideration. The Company's ongoing major or central operations consist of the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. The NIH and its various institutes are responsible for biomedical and public health research and provide major biomedical research funding to non-NIH research facilities and entities such as Navidea. While the Company will directly benefit from any knowledge gained from the project, there is also a public health benefit provided, which justifies the use of public funds in the form of the grants. Based on the nature of the Company's operations and the terms of the grant awards, Navidea does not have a vendor-customer relationship with the NIH and the grant awards are outside the scope of the revenue recognition standard. Accordingly, the revenue recognition standard need not be applied to the NIH grants. During the three-month periods ended March 31, 2022 and 2021, the Company recognized grant revenue of $0 and $1,251, respectively.

4. Stock-Based Compensation

For the three-month periods ended March 31, 2022 and 2021, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was $184,850 and $121,298, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2022 and 2021.

A summary of the status of our stock options as of March 31, 2022, and changes during the three-month period then ended, is presented below.

	Three Months Ended March 31, 2022			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding, January 1, 2022	919,790	$ 5.67	6.5	$ —
Granted	2,500	0.97		
Cancelled/Forfeited	(27,455)	6.29		
Expired	(6,185)	64.17		
Outstanding, March 31, 2022	888,650	$ 5.23	6.3	$ —
Exercisable, March 31, 2022	634,485	$ 6.73	5.1	$ —

The weighted average grant date fair value per stock option granted during the three-month period ended March 31, 2022 was $0.77. Key assumptions used in the Black-Scholes option pricing model for stock options granted during the three-month period ended March 31, 2022 were the Company's stock price, an expected volatility rate of 99.92%, a risk-free rate of 1.69%, and an expected life of 6.25 years.

A summary of the status of our unvested restricted stock as of March 31, 2022, and changes during the three-month period then ended, is presented below.

	Three Months Ended March 31, 2022	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested, January 1, 2022	95,000	$ 1.40
Vested	(2,500)	2.28
Unvested, March 31, 2022	92,500	$ 1.38

As of March 31, 2022, there was $161,015 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 1.65 years.

5. Loss Per Share

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

Diluted loss per common share for the three-month periods ended March 31, 2022 and 2021 excludes the effects of 1,310,974 and 1,751,794 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, 92,500 and 62,500 shares of unvested restricted stock for the three-month periods ended March 31, 2022 and 2021, respectively, were excluded in determining basic and diluted loss per share from continuing operations because such inclusion would be anti-dilutive.

6. Inventory

The components of inventory as of March 31, 2022 and December 31, 2021 are as follows:

	March 31, 2022	December 31. 2021
Materials	$ 214,028	$ 50,000
Finished goods	108,964	101,155
Total inventory	$ 322,992	$ 151,155

During the three-month period ended March 31, 2021, we allocated $4,054 of finished goods inventory for use in clinical trials. This transaction was recorded in research and development expense in the consolidated statements of operations.

7. Accounts Payable, Accrued Liabilities and Other

Accounts payable as of March 31, 2022 and December 31, 2021 includes an aggregate of $119,182 and $57,099, respectively, due to related parties for director fees. Accrued liabilities and other as of March 31, 2022 and December 31, 2021 includes an aggregate of $948,752 and $1,194,719, respectively, due to related parties for accrued separation costs, bonuses and benefits. The Company pays director fees in both cash and stock. As a result, the cash portion of director fees due are included in accounts payable and the stock portion are included in accrued liabilities and other in the consolidated balance sheet as of March 31, 2022 and December 31, 2021. Certain directors have elected to defer receipt of both cash and stock for director fees until at least July 1, 2022.

8. Notes Payable

IPFS Corporation

In November 2020, we prepaid $442,041 of insurance premiums through the issuance of a note payable to IPFS Corporation ("IPFS") with an interest rate of 3.5%. The note was payable in seven monthly installments of $63,888, with the final payment made in June 2021. In November 2021, we prepaid $565,760 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 4.36%. The note is payable in five monthly installments of $114,388, with the final payment due in April 2022.

Interest expense related to the IPFS notes payable totaled $3,712 and $2,770 during the three-month periods ended March 31, 2022 and 2021, respectively. The balance of the IPFS note was $113,974 as of March 31, 2022, and was included in notes payable, current in the condensed consolidated balance sheets.

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 $8,012. The current least term expires in June 2023.

In addition, we currently lease approximately 25,000 square feet of office space at 5600 Blazer Parkway, Dublin, Ohio, formerly our principal offices, at a monthly base rent of $28,149 in 2022. The current lease term expires in October 2022 with an option to extend for an additional five years. The Company does not intend to renew this lease. In June 2017, the Company executed a sublease arrangement for the Blazer 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. We also leased a vehicle at a monthly payment of $287, which expired in September 2021.

Total operating lease expense was $37,676 and $45,832 for the three-month periods ended March 31, 2022 and 2021, 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, 2022.

Maturity of Lease Liabilities	**Operating Lease Payments**
2022 (remaining)	$ 197,222
2023	19,699
2024	1,355
Total undiscounted operating lease payments	218,276
Less imputed interest	8,837
Present value of operating lease liabilities	$ 209,439
Balance Sheet Classification	
Current lease liabilities	$ 198,140
Noncurrent lease liabilities	11,299
Total operating lease liabilities	$ 209,439
Other Information	
Weighted-average remaining lease term for operating leases (years)	0.8
Weighted-average discount rate for operating leases	10.9%

Cash paid for amounts included in the present value of operating lease liabilities was $93,889 and $92,711 during the three-month periods ended March 31, 2022 and 2021, respectively, and is included in operating cash flows.

10. Commitments and Contingencies

We are subject to legal proceedings and claims that arise in the ordinary course of business. The amount of ultimate liability, if any, with respect to these actions is unknown.

CRG Litigation

As disclosed in the notes to the financial statements included in the Company's 2021 Form 10-K, 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 District Court of Harris County, Texas (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.

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

The Company has also been engaged in ongoing litigation with CRG in the Court of Common Pleas of Franklin County, Ohio (the "Ohio Court") related to Navidea's claims that the CRG Lenders fraudulently induced Navidea to enter into a settlement agreement and breached the terms of the same through certain actions taken by the CRG Lenders in connection with the GSA, pursuant to which Navidea agreed to pay up to $66.0 million to the CRG Lenders, as well as through actions and misrepresentations by CRG after the GSA was executed. The claims in that suit were for breach of contract, conversion and unjust enrichment against the CRG Lenders for their collection of more than $66.0 million, the maximum permitted under the GSA, and their double recovery of amounts paid as part of the $4.1 million paid in June 2016 and recovered again as part of the $66.0 million. CRG's double recovery and recovery of more than $66.0 million are due to CRG drawing the entire $7.1 million on the Cardinal Health 414 letter of credit. The CRG Lenders sought a Writ of Prohibition in the Ohio Supreme Court to prevent this case from moving forward, which was denied, and proceedings resumed in front of the Ohio Court. Following an unsuccessful mediation on May 7, 2019, Navidea moved for summary judgment on June 28, 2019. On November 27, 2019, the Ohio Court found that when CRG collected more than $66.0 million, they took an excess recovery and breached the GSA. The Ohio Court awarded approximately $4.3 million to Navidea, plus statutory interest from April 9, 2018, the date CRG drew on the Cardinal Health 414 letter of credit. The Ohio Court also found that there was no unjust enrichment or conversion by CRG since this was a matter of contract and only contract damages were appropriate. The decision was a final appealable order and terminated the case before the Ohio Court. On December 5, 2019, CRG filed a notice of appeal with Ohio's 10th District Court of Appeals regarding the judgment in favor of Navidea. The briefing of the appeal concluded on March 27, 2020, and oral argument on the appeal was held on September 23, 2020. On March 16, 2021, Ohio's 10th District Court of Appeals issued a decision which reversed the Ohio Court's November 27, 2019 ruling that CRG breached the GSA and its award of $4.3 million plus statutory interest to Navidea. The Ohio Court of Appeals held that the Ohio Court did not have jurisdiction to adjudicate Navidea's claims and therefore did not rule on the factual merits of Navidea's claims regarding CRG's recovery in excess of the contractually agreed maximum amount. The Ohio Supreme Court declined to hear the case so the Ohio litigation has concluded.

In April 2018, CRG asserted claims against Navidea and MT for alleged breaches of the GSA and the CRG Loan Agreement entered into by Navidea arising from the Navidea's challenge to CRG's drawing down on letters of credit in the full amount of $7.1 million which Navidea claims resulted in an overpayment of approximately $4.2 million under the CRG Loan Agreement. CRG also seeks declaratory judgment relief that essentially mirrors their claims for affirmative relief, i.e., that the Company breached the GSA and indemnification provision of the CRG 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 awarded as damages reasonable attorneys' fees in an amount, if any, to be determined at trial. The case is set for a bench trial on August 26, 2022. CRG has 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. Discovery has been completed and a motion to amend the interlocutory partial summary judgment is pending. The amount of ultimate liability, if any, with respect to this action is unknown.

Platinum Litigation

In November 2017, Platinum-Montaur commenced an action against the Company in the Supreme Court of the State of New York, County of New York (the "New York Supreme Court"), seeking damages of approximately $1.9 million purportedly due as of March 3, 2017, plus interest accruing thereafter. The claims asserted were for breach of contract and unjust enrichment in connection with funds received by the Company under the Platinum Loan Agreement. The action was subsequently removed to the United States District Court for the Southern District of New York. On October 31, 2018, the District Court granted judgment for Navidea and dismissed all claims in the case. The District Court stated that Platinum-Montaur had no standing to assert any contractual interest in funds that might be due under the Platinum Loan Agreement. The District Court also disagreed with Platinum-Montaur's claim of unjust enrichment on similar grounds and found that Platinum-Montaur lacked any sufficient personal stake to maintain claims against Navidea. The claims against Navidea were dismissed without prejudice on the grounds of lack of standing to pursue the claims asserted.

On November 30, 2018, Platinum-Montaur filed a notice of appeal with the United States Court of Appeals for the Second Circuit (the "Second Circuit") claiming that the District Court erred in dismissing Platinum-Montaur's claims for breach of contract and unjust enrichment. On January 22, 2019, Platinum-Montaur filed its brief in the Second Circuit, asking the Second Circuit to reverse the District Court and remand the case to the District Court for further proceedings. The Second Circuit held oral argument in this matter on September 5, 2019. On November 25, 2019, the Second Circuit issued a decision which remanded the case to the District Court for further consideration of whether the District Court had jurisdiction over the case following removal from the New York Supreme Court. The Second Circuit did not address the merits of Platinum-Montaur's allegations against Navidea. By agreement of the parties, the case was remanded from the District Court to the New York Supreme Court. Navidea filed a Motion to Dismiss on June 4, 2020, and on September 2, 2020, the New York Supreme Court granted the Motion to Dismiss. Platinum-Montaur filed a Notice of Appeal of the New York Supreme Court's decision on September 23, 2020 and the appeal was docketed with the Appellate Department-First Division. Platinum-Montaur perfected an appeal of the judgment in favor of the Company on or about June 28, 2021. In January 2022, Platinum and the Company settled their dispute and Platinum's lawsuit was dismissed. See Note 11.

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 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. and Dr. Michael S. Rosol. Mr. Scott 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 of directors, replacing Dr. Goldberg with Mr. Latkin as Chief Executive Officer of MT, terminating the sublicense between Navidea and MT, terminating certain research projects, and allowing MT intellectual property to revert back to Navidea, were not breaches of the Goldberg Agreement.

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

In addition, the District Court found Navidea's breach of fiduciary duty claim against Dr. Goldberg for conduct occurring more thanthree 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 ofthird-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 in light of the Delaware Court's decision datedJune 23, 2021 (described below). On October 14, 2021, the Magistrate Judge recommended that Navidea's motion for reconsideration be denied. OnMarch 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 periodSeptember 1, 2020 through March 31, 2022. The Company has opposed the fee application on numerous grounds and Dr. Goldberg's reply is due onMay 19, 2022. The matter will then be referred to the Magistrate Judge for resolution.

Fact discovery and expert discovery in the New York Action have been completed. The Company has moved to disqualify Dr. Goldberg's damages expert and briefing in the District Court was submitted on April 1, 2022. The District Court has not yet ruled on the Company's motion. The Company anticipates that once the District Court rules on the expert issues, the District Court will schedule briefing on summary judgment.

Delaware Litigation Involving Dr. Goldberg

On February 20, 2019, MT initiated a suit against Dr. Goldberg in the Court of Chancery of the State of Delaware (the "Delaware Court"), alleging, among other things, breach of fiduciary duty as a director and officer of MT and conversion, and to obtain a declaratory judgment that the transactions Dr. Goldberg caused MT to effect are void. On June 12, 2019, the Delaware Court found that Dr. Goldberg's actions werenot authorized in compliance with the Delaware General Corporate Law. Specifically, the Delaware Court found that Dr. Goldberg's creation of a new subsidiary of MT and the purported assignment by Dr. Goldberg of MT's intellectual property to that subsidiary were void. The Delaware Court's ruling follows the order on May 23, 2019 in the case, in which it found Dr. Goldberg in contempt of its prior order holding Dr. Goldberg responsible for the payment of MT's fees and costs to cure the damages caused by Dr. Goldberg's contempt.

On June 23, 2021, the Delaware Court ruled in favor of MT and against Dr. Goldberg, finding that Dr. Goldberg breached his fiduciary duties to MT. Specifically, the Delaware Court ruled: "Dr. Goldberg attempted to take for himself that which belonged to [MT]. In doing so, he breached his duty of loyalty to [MT] stockholders. [MT] was absolutely justified in bringing this action to remedy (in this case undo) the harm caused by Dr. Goldberg's misconduct." The Delaware Court disagreed with MT's arguments regarding damages and, other than awarding nominal damages, declined to award additional relief beyond that which it had previously granted. With respect to MT's claim for conversion, the Delaware Court found that the claim was not supported because "Dr. Goldberg confirmed that he currently doesnot own or possess any intellectual property related to either Navidea or [MT]" and that "any IP Dr. Goldberg created while at Navidea or any of its subsidiaries was and remains the property of Navidea and its subsidiaries." In addition, the Delaware Court denied Dr. Goldberg's motion to hold MT's directors and CEO in contempt, denied Dr. Goldberg's motion to dismiss the lawsuit against him, and granted MT's motion to dismiss Dr. Goldberg's petition to remove MT's board members. On December 9, 2021, Dr. Goldberg was ordered to reimburse MT in the amount of $66,796.33 and has paid that amount to MT. Neither party has appealed the Delaware Court's decision and the Delaware Court's decisions are now final.

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 wasnot 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 intwo out of its three most recent fiscal years, and (ii) $4.0 million or more if it has reported losses from continuing operations inthree 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 itsfive most recent fiscal years ended December 31, 2021.

The NYSE American has granted the Company a plan period throughJuly 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

As discussed in Note 10, Platinum and the Company settled their dispute and Platinum's lawsuit was dismissed inJanuary 2022. As part of the settlement, Platinum returned their six shares of MT Preferred Stock, representing60% of the noncontrolling interest in MT, to the Company. Prior to the settlement, the carrying amount of the noncontrolling interest in MT was $731,299. As a result of the settlement and the return ofsix shares of MT Preferred Stock, the Company recorded a reduction of the noncontrolling interest in MT and an increase in additional paid-in capital of $438,779.

On January 31, 2022, pursuant to the Certificate of Designations of the Series E Redeemable Convertible Preferred Stock datedMarch 2, 2021 ("Series E Preferred Stock"), the holder of the Series E Preferred Stock, John K. Scott, Jr., notified the Company that he was exercising his option to extend the Conversion Deadline (as defined therein) for an additional period of six months. See Note 16.

During the three-month periods endedMarch 31, 2022 and 2021, we issued 53,238 and 30,018 shares of our Common Stock as matching contributions to our401(k) Plan, which were valued at $44,720 and $76,846, respectively.

During the three-month period endedMarch 31, 2022, we issued 16,632 shares of our Common Stock to our employees as partial payment in lieu of cash for their2021 bonuses, which were valued at $16,965.

12. Stock Warrants

As of March 31, 2022, there are 422,324 warrants outstanding to purchase Navidea's Common Stock. The warrants are exercisable at prices ranging from $0.20 to $49.80 per share with a weighted average exercise price of $2.30 per share. The warrants have remaining outstanding terms ranging from 1.2 to 13.4 years.

13. Income Taxes

Income taxes are accounted for under the asset and liability method in accordance with Accounting Standards Codification740, *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 thannot 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, 2022 and December 31, 2021.

In assessing the realizability of DTAs, management considers whether it is more likely thannot that some portion or all of the DTAs willnot 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, 2022.

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, 2022 or December 31, 2021 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, 2022, tax years 2018-2021 remained subject to examination by federal and state tax authorities.

As of March 31, 2022, we had approximately $164.1 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 2022 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 ontwo 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, 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

Three Months Ended March 31, 2021	Diagnostics	Therapeutics	Corporate	Total
License revenue	$ 22,486	$ —	$ —	$ 22,486
Grant and other revenue	101,251	—	—	101,251
Total revenue	123,737	—	—	123,737
Research and development expenses	1,094,390	128,364	—	1,222,754
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	2,006	2,210,991	2,212,997
Depreciation and amortization (2)	6,040	—	11,708	17,748
Loss from operations (3)	(976,693)	(130,370)	(2,222,699)	(3,329,762)
Other income (4)	—	—	362,870	362,870
Net loss	(976,693)	(130,370)	(1,859,829)	(2,966,892)
Total assets, net of depreciation and amortization:				
United States	$ 160,669	$ —	$ 9,723,212	$ 9,883,881
International	193,194	—	—	193,194
Capital expenditures	—	—	—	—

(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 ($22,878 and $17,748 for the three-month periods ended March 31, 2022 and 2021, respectively).

(3) Income (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 extinguishment of debt, 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, 2022 and 2021, we paid interest of $3,712 and $2,900, respectively. During the three-month period ended March 31, 2021, we collected approximately $2.925 million of stock subscriptions which were received prior to the filing of our Annual Report on Form 10-K for the year ended December 31, 2020 and were included in stock subscriptions receivable in our consolidated balance sheet as of December 31, 2020. During the three-month periods ended March 31, 2022 and 2021, we issued 53,238 and 30,018 shares of our Common Stock as matching contributions to our 401(k) Plan, which were valued at $44,720 and $76,846, respectively. During the three-month period ended March 31, 2022, we issued 16,632 shares of our Common Stock to our employees as partial payment in lieu of cash for their 2021 bonuses, which were valued at $16,965.

16. Subsequent Events

The Company has evaluated events and transactions subsequent to March 31, 2022 and through the date these condensed consolidated financial statements were included in this Quarterly Report on Form 10-Q and filed with the SEC.

Rights Agreement

On April 7, 2022, the Company's Board of Directors adopted an NOL rights plan in the form of a Section 382 Rights Agreement ("Rights Agreement") to preserve and protect the Company's net operating loss carryforwards ("NOLs") and other tax assets. As of December 31, 2021, the Company had approximately $164 million of NOLs available to offset future federal taxable income.

Under the 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. 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. 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 Rights Agreement.

The rights issued under the Rights Agreement 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 Rights Agreement is no longer necessary or desirable for the preservation of NOLs or other tax benefits; (iii) thefirst 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 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.

Stock Exchange and Loan Agreement

On April 10, 2022, the Company entered into a Purchase 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. The outstanding balance of the loan, which is evidenced by a Bridge Note, will bear interest at a rate of 8% per annum, with payments of interest only to be made monthly over a period oftwo years. All outstanding principal and accrued and unpaid interest under the Bridge Note is due and payable on the second anniversary of the Purchase Agreement. The Company's obligations under the 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 a partial inducement for Mr. Scott to make the loan, at the closing, Mr. Scott agreed to deliver50,000 shares of Series E Preferred Stock, representing 100% of the outstanding Series E Preferred Stock, to the Company in exchange for the Company's issuance of1,740 shares of Series F Redeemable Convertible Preferred Stock ("Series F Preferred Stock") and 3,260 shares of Series G Redeemable Preferred Stock ("Series G Preferred Stock"). The number of shares of Common Stock that the Company may issue to the Investor upon conversion of the Series F Preferred stockmay not exceed that number of shares that would result in Mr. Scott owning more than 33.33% of the Company's then outstanding shares of Common Stock unless the Company obtains stockholder approval to issue more than the 33.33% cap. The closing of the loan and stock exchange took place onApril 12, 2022.

In connection with the Purchase Agreement, the Company entered into a Registration Rights Agreement with Mr. Scott, pursuant to which the Company agreed to file a registration statement with the SEC to register the resale of the shares issuable to Mr. Scott upon conversion of the Series F Preferred Stock.

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 global COVID-19 pandemic on our business, financial condition or prospects, including a decline in the volume of procedures using our products, potential delays and disruptions to global supply chains, manufacturing activities, logistics, operations, employees and contractors, the business activities of our suppliers, distributors, customers and other business partners, as well as the effects on worldwide economies, financial markets, social institutions, labor markets and healthcare systems;
- 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 ongoing COVID-19 pandemic and/or the current Russia-Ukraine conflict;
- our ability to successfully commercialize our drug candidates, including delays or disruptions related to the ongoing COVID-19 pandemic and/or 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 ongoing COVID-19 pandemic and/or 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. ("Navidea," the "Company," "our" or "we"), a Delaware corporation (NYSE American: NAVB), is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on our Manocept™ platform to enhance patient care by identifying the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and targeted treatment.

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

Our business is focused on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform, and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform. See Note 14 to the accompanying consolidated financial statements for more information about our business segments.

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.

During the ongoing COVID-19 global pandemic, the Company's primary concern is the safety of its employees, the employees of its clinical trial sites, and the patients enrolled in its clinical trials. The Company is working hard to mitigate any safety risk along with any long-term impact on its clinical development programs. We do not believe there has been a significant impact to the Company's clinical development and regulatory timelines resulting from the ongoing COVID-19 global pandemic. However, the COVID-19 outbreak delayed enrollment in our NAV3-32 clinical study in the United Kingdom due to national COVID-19-related shutdowns. In addition, the regulatory approval process in India was delayed by the impact of COVID-19 in that country.

As 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 recently launched 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, nonalcoholic steatohepatitis, inflammatory bowel disease, 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 two 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, and the 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 the MAN-DOX series and MAN-DEX series agents, along with the concomitant analytical standards, to provide material for current and planned preclinical animal studies and future clinical trials. Evaluation of advanced MAN-DOX and MAN-DEX constructs have been successfully performed in human macrophage cell culture assays with MAN-DOX 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. These studies have been combined and submitted for peer review publication and full published results will follow.

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 MCT03938636). 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 upcoming 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.

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 has begun. 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.

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, and has achieved full enrollment, with a manuscript submitted.

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 has also been awarded a $225,000 phase 1 Small Business Technology Transfer grant (1R41HL147640-01A1) entitled *Gallium 68 Tilmanocept for PET Imaging of Atherosclerosis Plaques*. This grant supported a research collaboration between Navidea and Dr. Suzanne Lapi of the University of Alabama Birmingham evaluating a mouse model of atherosclerosis. This work has 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. As of January 2022, all images have been acquired with efforts now focused on data analyses.

Kaposi's Sarcoma

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

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 providing the background data sets for qualification review with the FDA/CDER. Additional meetings have taken place and the pursuit of this qualification is ongoing.

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

The Company has been developing Manocept platform drug delivery constructs that carry various payloads including doxorubicin and dexamethasone. 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. The most advanced drug delivery construct carries a doxorubicin payload and is now in its third generation of chemical synthesis protocol design. This third-generation doxorubicin carrying construct has been extensively evaluated in human macrophage cell culture assays and in three experiments using syngeneic mouse cancer models. These experiments show that at treatment doses below what is required to kill macrophages, the doxorubicin-carrying constructs dramatically alters the immunological behavior of macrophages, making them more proinflammatory. In one of the syngeneic mouse tumor experiments, the MAN-DOX construct significantly synergized the activity of another anticancer therapy producing anti-tumor activity that was greater than either treatment alone. Results from this study were presented at the New York Academy of Sciences Frontiers in Cancer Immunotherapy 2021 conference on May 14, 2021. Near-term experiments with the Manocept doxorubicin construct include further studies in macrophage cell culture, additional syngeneic mouse tumor models, and a toxicity study in rats. Work involving a second generation Manocept dexamethasone-carrying construct and efforts has progressed to evaluations in human macrophage culture assays. Efforts developing Manocept constructs with different payloads are ongoing. Three new Manocept constructs carrying payloads other than doxorubicin or dexamethasone have progressed to evaluations in macrophage cell culture assays.

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. 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 $1.2 million in total on research and development ("R&D") activities during the three-month periods ended March 31, 2022 and 2021. 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 [a]	**2022**	**2021**
Manocept Platform – Diagnostics [b]	$ 364,547	$ 677,229
Manocept Platform – Therapeutics	179,367	128,365
Tc99m Tilmanocept [b]	1,648	7,407

(a) Certain development program expenditures were offset by grant reimbursement revenues totaling $1,000 during the three-month period ended March 31, 2021.

(b) Certain 2021 amounts have been reclassified from Tc99m Tilmanocept to Manocept Platform – Diagnostics to conform to the 2022 presentation.

We expect to continue the advancement of our efforts with our Manocept platform during the remainder of 2022. We currently expect our total R&D expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be higher in 2022 than in 2021. However, the ongoing global COVID-19 pandemic has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities and our supply chain. For example, the COVID-19 outbreak delayed enrollment in our NAV3-32 clinical study in the United Kingdom due to national COVID-19-related shutdowns. In addition, the regulatory approval process in India was delayed by the impact of COVID-19 in that country. The COVID-19 pandemic may delay enrollment in our future clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may be unwilling to enroll in our future trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver clinical drug supplies on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

The extent to which the ongoing global COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and spread of COVID-19, the actions taken by federal, state and local governmental authorities, both domestic and foreign, as well as private parties, to contain or treat its impact, and other events outside of our control. The COVID-19 pandemic has adversely affected economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations, including our ability to obtain additional funding.

Tc99m tilmanocept is approved by the European Medicines Agency 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.

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, therefore the discussion of our revenue focuses on the grant and other revenue and our operating variances focus on our product development programs and the supporting general and administrative expenses.

Three Months Ended March 31, 2022 and 2021

License Revenue. During the first quarter of 2021, we recognized license revenue of $22,000 related to net transitional sales from SpePharm in Europe. No license revenue was recorded during the first quarter of 2022.

Grant and Other Revenue. During the first quarter of 2021, we recognized grant and other revenue of $101,000. Grant revenue of $1,000 during the first quarter of 2021 was primarily related to a Small Business Technology Transfer grant from the NIH supporting Manocept development. Other revenue during the first quarter of 2021 included $100,000 from Alseres for the partial recovery of debts previously written off in 2015. No grant or other revenue was recognized during the first quarter of 2022.

Research and Development Expenses. R&D expenses decreased $54,000, or 4%, at approximately $1.2 million during the first quarters of 2022 and 2021. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased Manocept diagnostic development costs of $313,000 including decreased manufacturing-related activities and decreased clinical trial costs; and (ii) decreased Tc99m tilmanocept development costs of $6,000, primarily European regulatory consulting expenses; offset by (iii) increased Manocept therapeutic development costs of $51,000 including increased preclinical and clinical development costs and increased manufacturing-related activities. The net decrease in R&D expenses also included decreased regulatory consulting expenses of $39,000 offset by increased employee compensation including fringe benefits and incentive-based awards of $235,000 and increased recruiting fees of $17,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $421,000, or 19%, to $1.8 million during the first quarter of 2022 from $2.2 million during the same period in 2021. Decreased employee compensation including fringe benefits and incentive-based awards of $453,000, decreased investor relations costs of $48,000, decreased general office expenses of $26,000, decreased travel of $14,000, decreased franchise taxes of $12,000 and decreased legal and professional services of $11,000 were offset by increased director fees of $61,000 related to additional board members and increased board compensation rates, losses on the abandonment of certain intellectual property of $48,000 and increased insurance costs of $42,000.

Other Income (Expense). Other expense, net, was $8,000 during the first quarter of 2022 compared to other income, net, of $363,000 during the same period in 2021. During the first quarters of 2022 and 2021, we recognized interest expense of $4,000 and $3,000, respectively. During the first quarter of 2021, we recognized a gain on extinguishment of debt of $366,000 resulting from forgiveness of our PPP loan.

Liquidity and Capital Resources

Cash balances decreased to $1.2 million as of March 31, 2022 from $4.2 million as of December 31, 2021. The net decrease was primarily due to cash used to fund our operations of $2.6 million, payments on notes payable of $339,000, patent and trademark costs of $76,000 and purchases of equipment of $42,000.

Operating Activities. Cash used in operations was $2.6 million during the first quarter of 2022 compared to $3.1 million used during the same period in 2021.

Receivables increased to $116,000 as of March 31, 2022 from $93,000 as of December 31, 2021, primarily due to achievement of a milestone pursuant to our license and distribution agreement in India of $100,000, offset by the receipt of receivables due from related parties.

Inventory increased to $323,000 as of March 31, 2022 from $151,000 as of December 31, 2021, primarily due to the purchase of materials to be used in the manufacturing process.

Prepaid expenses and other current assets decreased to $667,000 as of March 31, 2022 from $908,000 as of December 31, 2021, primarily due to normal amortization of prepaid insurance and application of an upfront contract payment of $56,000 related to a clinical study.

Accounts payable increased to $1.6 million as of March 31, 2022 from $1.4 million as of December 31, 2021. Net increased payables due for legal and professional services and deferred board of director fees were offset by decreased payables due for clinical development activities. Accrued liabilities and other current liabilities decreased to $3.0 million as of March 31, 2022 from $3.1 million as of December 31, 2021. Net decreased accruals related to the separation of our former Chief Executive Officer, employee benefits, incentive-based compensation, legal and professional services, and clinical development activities were offset by net increased accruals related to Manocept development costs. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our development activity related to the Manocept platform.

Investing Activities. Investing activities used $118,000 during the first quarter of 2022 compared to $67,000 used during the same period in 2021. Patent and trademark costs used $76,000 and purchases of property and equipment used $42,000 during the first quarter of 2022. Patent and trademark costs used $67,000 during the first quarter of 2021.

Financing Activities. Financing activities used $339,000 during the first quarter of 2022 compared to $8.0 million provided during the same period in 2021. The $339,000 used by financing activities in the first quarter of 2022 consisted of principal payments on financed insurance premiums of $339,000. The $8.0 million provided by financing activities in the first quarter of 2021 consisted primarily of proceeds from issuance of preferred stock of $8.2 million offset by principal payments on financed insurance premiums of $189,000 and costs of issuing preferred stock of $19,000.

Bridge Loan and Preferred Stock Exchange

On April 10, 2022, the Company entered into a Stock Exchange and Loan Agreement (the “Purchase Agreement”) with John K. Scott, Jr., the current Vice Chairman of our Board of Directors, 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. The outstanding balance of the loan, which is evidenced by a Secured Term Note (the “Bridge Note”), will bear 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 Bridge Note is due and payable on the second anniversary of the Purchase Agreement. The Company’s obligations under the 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. See Notes 2 and 16 to the accompanying consolidated financial statements.

As consideration and a partial inducement for Mr. Scott to make the Bridge Note, Mr. Scott agreed to deliver 50,000 shares of Series E Redeemable Convertible Preferred Stock (“Series E Preferred Stock”), representing 100% of the outstanding Series E Preferred Stock, to the Company in exchange for the Company’s issuance of 1,740 shares of Series F Redeemable Convertible Preferred Stock (“Series F Preferred Stock”) and 3,260 shares of Series G Redeemable Preferred Stock (“Series G Preferred Stock”). The number of shares of Common Stock that the Company may issue to Mr. Scott upon conversion of the Series F Preferred stock may not exceed that number of shares that would result in Mr. Scott owning more than 33.33% of the Company’s then outstanding shares of Common Stock unless the Company obtains stockholder approval to issue more than the 33.33% cap. See Notes 11 and 16 to the condensed consolidated financial statements.

CRG Litigation

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

Platinum Litigation

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

Goldberg Agreement and Litigation

See Notes 2 and 10 to the accompanying 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 2022 on development of products based on the Manocept platform. Although management believes that it will be able to achieve this objective, it is subject to a number of variables beyond our control, including the nature and timing of any partnering opportunities, the ability to modify contractual commitments made in connection with these programs, and the timing and expense associated with suspension or alteration of clinical trials, and consequently we may need to seek additional financing in order to support our planned development programs.

We will continue to evaluate our timelines, strategic needs, and balance sheet requirements. If we attempt to raise additional capital through debt, royalty, equity or otherwise, we may not be successful in doing so on terms acceptable to the Company, if at all. Although on February 14, 2022 we filed a registration statement with the Securities and Exchange Commission to register the sale of up to $35 million of Company Common Stock pursuant to a rights offering, the terms and timing of such rights offering have not yet been determined by the Company and there is no assurance that such rights offering will occur Further, we may not be able to gain access and/or be able to secure new sources of funding, identify new development opportunities, successfully obtain regulatory approval for and commercialize new products, achieve significant product revenues from our products, or achieve or sustain profitability in the future.

The Company is currently engaged in litigation with Dr. Goldberg and CRG. The amount of ultimate liability, if any, with respect to these actions is unknown.

In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. The COVID-19 pandemic may negatively impact the Company's operations, including possible effects on its financial condition, ability to access the capital markets on attractive terms or at all, liquidity, operations, suppliers, industry, and workforce. We do not believe there has been a significant impact to the Company's clinical development and regulatory timelines resulting from the ongoing COVID-19 global pandemic. However, the COVID-19 outbreak delayed enrollment in our NAV3-32 clinical study in the United Kingdom due to national COVID-19-related shutdowns. In addition, the regulatory approval process in India has been delayed by the impact of COVID-19 in that country. The COVID-19 pandemic has adversely affected economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations, including our ability to obtain additional funding. The Company will continue to evaluate the impact that the COVID-19 pandemic could have on the operations, financial position, and the results of operations and cash flows during fiscal year 2022 and beyond.

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 2022 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 investments, 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. No adjustments have been made to the accompanying condensed consolidated financial statements as a result of this uncertainty. See Note 2 to the accompanying consolidated financial statements.

As of March 31, 2022, we had no off-balance sheet arrangements.

Recent Accounting Standards

See Note 1(h) to the accompanying 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, 2021, filed with the SEC on March 28, 2022 ("2021 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 generate revenue from a grant to support a product development initiative. 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 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.

Series D and Series E Convertible Preferred Stock. The Company evaluated the provisions of the Series D and Series E Preferred Stock under Accounting Standards Codification ("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*." Based on this evaluation, the Company determined that the Series D and Series E Preferred Stock are not mandatorily redeemable financial instruments and any obligation to issue a variable number of shares of Common Stock is not unconditional. Accordingly, the Series D and Series E Preferred Stock should be classified as equity. Neither the embedded conversion option nor the embedded call option meet the criteria to be separated from the Series D or Series E Preferred stock and thus these features should not be bifurcated and accounted for as derivatives. Additionally, the Series D Preferred Stock contains a beneficial conversion feature ("BCF"). Following the January 1, 2021 adoption of Accounting Standards Update ("ASU") No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, no BCF is recorded in the consolidated financial statements. Finally, the Company determined that the Series D and Series E Preferred Stock do not contain conversion features that could result in the Company being required to redeem a portion of the shares converted, thus the Series D and Series E Preferred Stock should not be classified in mezzanine equity.

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 2021 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, including our Executive Leadership Committee which consists of our Chief Medical Officer (principal executive officer), Vice President of Operations and Vice President of Finance and Administration (principal financial and accounting officer), we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of March 31, 2022. 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, 2022, 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 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 2021 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 16, 2021

By: */s/ Michael S. Rosol*

Michael S. Rosol, Ph.D.
Chief Medical Officer
(Principal Executive Officer)

By: */s/ Erika L. Eves*

Erika L. Eves
Vice President, Finance and Administration
(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, Michael S. Rosol, Ph.D., 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 16, 2022

/s/ Michael S. Rosol
Michael S. Rosol
Chief Medical Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Erika L. Eves, 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 16, 2022

/s/ Erika L. Eves
Erika L. Eves
Vice President, Finance and Administration
(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, 2022 as filed with the Securities and Exchange Commission (the "Report"), the undersigned, Michael S. Rosol, Ph.D., Senior Vice President and Chief Medical Officer (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 16, 2022

/s/ Michael S. Rosol
Michael S. Rosol, Ph.D.
Chief Medical Officer
(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, 2022 as filed with the Securities and Exchange Commission (the "Report"), the undersigned, Erika L. Eves, Vice President of Finance and Administration (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 16, 2022

/s/ Erika L. Eves
Erika L. Eves
Vice President, Finance and Administration
(Principal Financial and Accounting Officer)