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 June 30, 2021

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

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:30,163,245 shares of common stock, par value $.001 per share (as of the close of business on August 6, 2021).

NAVIDEA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	June 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,114,103	$ 2,670,495
Stock subscriptions and other receivables	2,400,238	2,987,319
Inventory	178,830	169,798
Prepaid expenses and other	350,239	700,716
Total current assets	10,043,410	6,528,328
Property and equipment	848,085	845,379
Less accumulated depreciation and amortization	731,098	713,217
Property and equipment, net	116,987	132,162
Right-of-use lease assets	458,280	458,280
Less accumulated amortization	269,142	208,185
Right-of-use lease assets, net	189,138	250,095
License agreements, patents and trademarks	851,929	747,863
Less accumulated amortization	147,346	127,622
License agreements, patents and trademarks, net	704,583	620,241
Other assets	227,192	227,192
Total assets	$ 11,281,310	$ 7,758,018

(continued)

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

	June 30, 2021 (unaudited)	December 31, 2020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,080,070	$ 1,161,717
Accrued liabilities and other	2,630,747	2,512,994
Notes payable	—	745,443
Lease liabilities, current	313,852	294,951
Total current liabilities	4,024,669	4,715,105
Lease liabilities, net of current portion	120,471	296,006
Deferred revenue	700,000	700,000
Total liabilities	4,845,140	5,711,111
Commitments and contingencies (See Note 11)		
Stockholders' equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding as of June 30, 2021 and December 31, 2020	—	—
Series D preferred stock subscribed; $.001 par value, 22,077 and 103,000 shares subscribed as of June 30, 2021 and December 31, 2020, respectively	22	132
Series D preferred stock subscriptions receivable	—	(10,300,000)
Series E preferred stock; $.001 par value, 50,000 shares authorized; 50,000 and 0 shares outstanding as of June 30, 2021 and December 31, 2020, respectively	50	—
Common stock; $.001 par value; 300,000,000 shares authorized; 30,145,718 and 27,149,691 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	221,142	218,146
Common stock subscribed; $.001 par value, 0 and 995,000 shares subscribed as of June 30, 2021 and December 31, 2020, respectively	—	995
Common stock subscriptions receivable	—	(4,975,000)
Additional paid-in capital	370,181,268	375,428,014
Accumulated deficit	(364,697,612)	(359,056,683)
Navidea stockholders' equity	5,704,870	1,315,604
Noncontrolling interest	731,300	731,303
Total stockholders' equity	6,436,170	2,046,907
Total liabilities and stockholders' equity	$ 11,281,310	$ 7,758,018

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Royalty revenue	$ —	$ 8,920	$ —	$ 24,141
License revenue	13,063	—	35,549	—
Grant and other revenue	247,983	262,181	349,234	403,232
Total revenue	261,046	271,101	384,783	427,373
Cost of revenue	—	357	—	966
Gross profit	261,046	270,744	384,783	426,407
Operating expenses:				
Research and development	1,498,056	1,281,779	2,720,810	2,281,048
Selling, general and administrative	1,432,610	1,329,591	3,663,355	3,157,345
Total operating expenses	2,930,666	2,611,370	6,384,165	5,438,393
Loss from operations	(2,669,620)	(2,340,626)	(5,999,382)	(5,011,986)
Other (expense) income:				
Interest income (expense), net	1,266	15,343	(1,609)	12,971
Gain on extinguishment of debt	—	—	366,000	—
Other, net	(5,686)	(336)	(5,941)	(212)
Total other (expense) income, net	(4,420)	15,007	358,450	12,759
Net loss	(2,674,040)	(2,325,619)	(5,640,932)	(4,999,227)
Loss (income) attributable to noncontrolling interest	1	1	3	(1)
Deemed dividend on Series C Preferred Stock beneficial conversion feature	—	(77,778)	—	(77,778)
Net loss attributable to common stockholders	$ (2,674,039)	$ (2,403,396)	$ (5,640,929)	$ (5,077,006)
Loss attributable to common stockholders per common share (basic and diluted)	$ (0.09)	$ (0.11)	$ (0.20)	$ (0.24)
Weighted average shares outstanding	29,117,832	22,759,393	28,531,660	21,481,514

See accompanying notes to condensed consolidated financial statements.

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

For the Six Months Ended June 30, 2021

	Preferred Stock		Preferred Stock Subscribed		Preferred Stock Subscriptions	Common Stock Issued		Common Stock Subscribed		Common Stock Subscriptions	Additional Paid-In	Accumulated	Non-controlling	
	Shares	Amount	Shares	Amount	Receivable	Shares	Amount	Shares	Amount	Receivable	Capital	Deficit	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
Issued Series D Preferred Stock	23,000	23	(23,000)	(23)	1,800,000	—	—	—	—	—	—	—	—	1,800,000
Issued stock upon conversion of Series D Preferred Stock	(23,000)	(23)	—	—	—	1,437,531	1,437	—	—	—	(1,414)	—	—	—
Series D Preferred Stock subscribed (See Note 12)	—	—	(55,423)	(56)	7,750,000	—	—	—	—	—	(5,542,245)	—	—	2,207,699
Incurred costs related to Series E Preferred Stock	—	—	—	—	—	—	—	—	—	—	(50,671)	—	—	(50,671)
Issued stock upon stock option exercise	—	—	—	—	—	2,000	2	—	—	—	2,118	—	—	2,120
Reversal of common stock subscribed	—	—	—	—	—	—	—	(995,000)	(995)	4,975,000	(4,974,005)	—	—	—
Stock compensation expense	—	—	—	—	—	—	—	—	—	—	142,180	—	—	142,180
Net loss	—	—	—	—	—	—	—	—	—	—	—	(2,764,039)	(1)	(2,674,040)
Balance, June 30, 2021	50,000	$ 50	22,077	$ 22	$ —	30,145,718	$221,142	—	$ —	$ —	$370,181,268	$(364,697,612)	$ 731,300	$ 6,436,170

(continued)

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

For the Six Months Ended June 30, 2020

	Series C Convertible Preferred Stock		Common Stock		Common Stock Subscribed		Common Stock Subscriptions Receivable	Additional Paid-In Capital	Accumulated Deficit	Non-controlling Interest	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, January 1, 2020	—	$ —	19,234,960	$ 210,232	902,162	$ 902	$ —	$ 345,847,676	$ (347,671,102)	$ 731,303	$ (880,989)
Issued stock in payment of services	—	—	3,810	4	—	—	—	4,797	—	—	4,801
Issued stock in payment of employee bonuses	—	—	53,315	53	—	—	—	64,458	—	—	64,511
Issued stock pursuant to private placement	—	—	902,162	902	(902,162)	(902)	—	—	—	—	—
Issued stock pursuant to registered direct offering, net of issuance costs of $150,000	—	—	1,000,001	1,000	—	—	—	699,000	—	—	700,000
Stock subscribed in connection with private placement	—	—	—	—	2,373,529	2,374	(912,500)	2,015,126	—	—	1,105,000
Stock subscribed in connection with registered direct offering	—	—	—	—	647,058	647	—	549,353	—	—	550,000
Stock compensation expense	—	—	—	—	—	—	—	39,246	—	—	39,246
Net loss	—	—	—	—	—	—	—	—	(2,673,610)	2	(2,673,608)
Balance, March 31, 2020	—	—	21,194,248	212,191	3,020,587	3,021	(912,500)	349,219,656	(350,344,712)	731,305	(1,091,039)
Issued restricted stock	—	—	10,000	10	—	—	—	—	—	—	10
Issued stock pursuant to registered direct offering	—	—	647,058	647	(647,058)	(647)	—	—	—	—	—
Issued stock pursuant to private placement	—	—	1,911,800	1,912	(1,911,800)	(1,912)	520,030	—	—	—	520,030
Issued stock to 401(k) plan	—	—	32,651	33	—	—	—	39,801	—	—	39,834
Issued stock upon exercise of warrants	—	—	300,595	300	—	—	—	(300)	—	—	—
Issued stock in payment of employee bonuses	—	—	40,844	41	—	—	—	106,970	—	—	107,011
Issued Series C Convertible Preferred Stock	70,000	70	—	—	—	—	—	699,930	—	—	700,000
Deemed dividend on Series C Preferred Stock	—	—	—	—	—	—	—	77,778	(77,778)	—	—
Issued stock upon conversion of Series C Preferred Stock	(70,000)	(70)	410,765	411	—	—	—	(341)	—	—	—
Stock subscribed in connection with private placement	—	—	—	—	—	—	392,470	—	—	—	392,470
Stock compensation expense	—	—	—	—	—	—	—	34,588	—	—	34,588
Net loss	—	—	—	—	—	—	—	—	(2,325,618)	(1)	(2,325,619)
Balance, June 30, 2020	—	$ —	24,547,961	$ 215,545	461,729	$ 462	$ —	$ 350,178,082	$ (352,748,108)	$ 731,304	$ (1,622,715)

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (5,640,932)	$ (4,999,227)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	37,606	36,099
Non-cash lease expense	60,957	60,010
Stock compensation expense	263,478	73,834
Gain on extinguishment of debt	(366,000)	—
Value of stock issued to 401(k) plan for employer matching contributions	76,846	39,834
Value of stock issued in payment of employee bonuses	—	171,522
Value of stock issued in payment of services	—	4,801
Changes in operating assets and liabilities:		
Receivables	(130,218)	756,622
Inventory	(9,032)	—
Prepaid expenses and other assets	350,477	866,070
Accounts payable	(81,647)	48,842
Accrued and other liabilities	71,825	(71,232)
Lease liabilities	(156,634)	(139,800)
Deferred revenue	45,928	166,805
Net cash used in operating activities	(5,477,346)	(2,985,820)
Cash flows from investing activities:		
Payments for purchases of equipment	(2,707)	(8,406)
Patent and trademark costs	(104,067)	(115,271)
Net cash used in investing activities	(106,774)	(123,677)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, including collection of stock subscriptions receivable	10,475,000	700,000
Payment of preferred stock issuance costs	(69,962)	—
Proceeds from issuance of common stock	2,133	3,025,040
Payment of common stock issuance costs	—	(150,000)
Proceeds from note payable	—	366,000
Principal payments on notes payable	(379,443)	(261,701)
Net cash provided by financing activities	10,027,728	3,679,339
Net increase in cash and cash equivalents	4,443,608	569,842
Cash and cash equivalents, beginning of period	2,670,495	1,047,159
Cash and cash equivalents, end of period	$ 7,114,103	$ 1,617,001

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 June 30, 2021 and for the three-month and six-month periods ended June 30, 2021 and 2020 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 prior period amounts also have been reclassified to conform to the current year's presentation. In addition, 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 ("SEC"). The balances as of June 30, 2021 and the results for the interim periods are not necessarily indicative of results to be expected for the year. The condensed consolidated financial statements should be read in conjunction with Navidea's audited consolidated financial statements for the year ended December 31, 2020, which were included as part of our Annual Report on Form10-K.

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

b. Financial Instruments and Fair Value: The following methods and assumptions were used to estimate the fair value of each class of financial instruments:

(1) *Cash and cash equivalents, stock subscriptions and other receivables, and accounts payable:* The carrying amounts approximate fair value because of the short maturity of these instruments.

(2) *Notes payable:* The carrying value of our debt as of June 30, 2021 and December 31, 2020 primarily consisted of the face amount of the notes plus accrued interest. As of June 30, 2021 and December 31, 2020, the fair value of our notes payable was approximately $0 and $745,000, respectively, both amounts equal to the carrying value of the notes payable. See Note 9.

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

We also earn revenues related to our licensing and distribution agreements. The consideration we are eligible to receive under our licensing and distribution agreements typically includes upfront payments, reimbursement for research and development costs, milestone payments, and royalties. Each licensing and distribution agreement is unique and requires separate assessment in accordance with current accounting standards. See Note 3.

d. Leases: All of our leases are operating leases and are included in right-of-use lease assets, current lease liabilities and noncurrent lease liabilities on our condensed consolidated balance sheets. These assets and liabilities are recognized at the commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates or implicit rates, when readily determinable. The discount rates used for each lease were based principally on the Platinum debt, which was secured and outstanding for most of 2018. We used a "build-up" method where the approach was to estimate the risk/credit spread priced into the debt rate and then adjust that for the remaining term of each lease. Additionally, some market research was completed on the Company's peer group. Short-term operating leases which have an initial term of 12 months or less are not recorded on the condensed consolidated balance sheets. Lease expense for operating leases is recognized on a straight-line basis over the lease term. Lease expense is included in selling, general and administrative expenses on our condensed consolidated statements of operations. See Note 10.

e. **Convertible Preferred Stock:** The Company evaluated the provisions of the Series C, Series D and Series E Convertible 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 neither the Series C, Series D nor Series E Preferred Stock is a mandatorily redeemable financial instrument and any obligation to issue a variable number of shares of Common Stock is not unconditional. Accordingly, the Series C, 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 C, Series D or Series E Preferred stock and thus these features should not be bifurcated and accounted for as derivatives. Additionally, the Series C and Series D Preferred Stock contain a beneficial conversion feature ("BCF"). Prior to the adoption of Accounting Standards Update ("ASU") No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, effective January 1, 2021, the BCF resulted in an increase to additional paid-in capital and a discount on the Series C and Series D Preferred Stock. The discounts on the Series C and Series D Preferred Stock were considered to be fully amortized at the date of issuance because the Series C and Series D Preferred Stock are immediately convertible, resulting in a deemed dividend at the date of issuance for the amount of the BCF. Finally, the Company determined that the Series D and Series E Preferred Stock does 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. See Note 12.

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

In August 2020, the FASB issued ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. ASU 2020-06 was issued to reduce the complexity associated with accounting for certain financial instruments with characteristics of liabilities and equity. ASU 2020-06 reduces the number of accounting models for convertible debt instruments and convertible preferred stock and improves the disclosures for convertible instruments and related earnings-per-share ("EPS") guidance. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance. ASU 2020-06 is effective for public business entities except smaller reporting companies for annual and interim reporting periods beginning after December 15, 2021, and for annual and interim reporting periods beginning after December 15, 2023 for all other entities. Early adoption is permitted, but the guidance must be adopted as of the beginning of a fiscal year. We adopted ASU 2020-06 effective January 1, 2021 using the modified retrospective method. The adoption of ASU 2020-06 did not result in a cumulative effect adjustment to retained earnings.

g. **Recently Issued Accounting Standards:** In May 2021, the FASB Issued 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. We do not expect the adoption of ASU 2021-04 to have a material impact on our condensed consolidated financial statements.

2. Liquidity

As disclosed in the notes to the financial statements included in the Company's Annual Report on 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 which Platinum-Montaur was seeking damages of approximately $1.9 million plus interest. See Note 11.

In addition, the Company is engaged in ongoing litigation with our former President and Chief Executive Officer, Dr. Michael Goldberg. See Note 11.

The Company has also been engaged in ongoing litigation with Capital Royalty Partners II L.P. (“CRG”) and pursuing recovery of approximately $4.3 million and other damages. See Note 11.

On August 30, 2020, the Company entered into a Stock Purchase Agreement (the “Common Stock Purchase Agreement”) with each of the investors named therein (the “Investors”), pursuant to which the Investors agreed to purchase from the Company, up to $25.0 million in shares of the Company’s common stock, par value $0.001 per share (“Common Stock”). As of the date of filing of this Quarterly Report on Form 10-Q, we have received only $25,000 of the $5.0 million that is currently owed under the Common Stock Purchase Agreement. During the second quarter of 2021, the Company determined that it is unlikely that the remaining $4.975 million will ever be collected. Accordingly, the common stock subscription receivable was reversed from the condensed consolidated balance sheet as of June 30, 2021. We are continuing to evaluate our rights and remedies under that agreement. See Note 12.

On August 31, 2020, the Company entered into a Stock Purchase Agreement and Letter of Investment Intent (the “Series D Preferred Stock Purchase Agreement”) with Keystone Capital Partners, LLC (“Keystone”) pursuant to which the Company agreed to issue to Keystone 150,000 shares of newly-designated Series D Redeemable Convertible Preferred Stock (the “Series D Preferred Stock”) for an aggregate purchase price of $15.0 million. Pursuant to the Series D Preferred Stock Purchase Agreement, Keystone agreed to purchase Series D Preferred Stock in amounts to be determined by Keystone in one or more closings before the end of the nine-month period following the date when the Company’s prospectus supplement to its existing registration statement on Form S-3 was filed with the SEC. On July 8, 2021 (the “Amendment Effective Date”), the Company entered into an Amendment to Stock Purchase Agreement and Letter of Investment Intent (the “Series D Amendment”) with Keystone pursuant to which Keystone purchased 22,077 shares of Series D Preferred Stock for an aggregate purchase price of approximately $2.2 million. Prior to the Amendment Effective Date, Keystone had purchased 72,500 shares of Series D Preferred Stock pursuant to the Series D Preferred Stock Purchase Agreement, leaving a remaining balance of 77,500 shares of Series D Preferred Stock. After purchasing the 22,077 remaining shares, Keystone has no further right or obligation to purchase shares of Series D Preferred Stock. Accordingly, the Series D Preferred Stock subscription receivable was reduced to approximately $2.2 million on the condensed consolidated balance sheet as of June 30, 2021. The Series D Preferred Stock is convertible into a maximum of 5,147,000 shares of Common Stock. See Notes 12 and 17.

On March 2, 2021, the Company entered into a Stock Purchase Agreement and Letter of Investment Intent (the “Series E Preferred Stock Purchase Agreement”) with an existing accredited investor, John K. Scott, Jr. pursuant to which the Company issued to Mr. Scott in a private placement transaction 50,000 shares of newly-designated Series E Redeemable Convertible Preferred Stock (the “Series E Preferred Stock”) for an aggregate purchase price of $5.0 million. The Series E Preferred Stock is convertible into a maximum of 2,173,913 shares of Common Stock. As of the date of filing of this Quarterly Report on Form 10-Q, none of the Series E Preferred Stock has been converted. See Note 12.

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

The Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) was enacted on March 27, 2020. Among the provisions contained in the CARES Act was the creation of the Paycheck Protection Program (“PPP”) that provides for Small Business Administration (“SBA”) Section 7(a) loans for qualified small businesses. PPP loan proceeds are available to be used to pay for payroll costs, including salaries, commissions, and similar compensation, group health care benefits, and paid leaves; rent; utilities; and interest on certain other outstanding debt. On May 18, 2020, Fifth Third Bank (the “Lender”) funded a loan to the Company in the amount of $366,000 under the SBA’s PPP (the “PPP Loan”). In accordance with the loan forgiveness requirements of the CARES Act, the Company used the proceeds from the PPP Loan primarily for payroll costs, rent and utilities. On February 23, 2021, the Lender notified the Company that the entire PPP Loan amount of $366,000 was forgiven. See Note 9.

We do not believe there has been 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 Company has experienced recurring net losses and has used significant cash to fund its operations. The Company has considerable discretion over the extent of development project expenditures and has the ability to curtail the related cash flows as needed. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of funding, including collaborations, potential equity investments, and additional grant funding that can augment the balance sheet. However, 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.

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. The Company has license and distribution agreements in place in India and China, however Tc99 tilmanocept has not been approved in either of those markets. OnMay 11, 2020, the Company terminated its license and distribution agreement in Europe and Australia.

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.

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

Up-front and milestone payments received related to our license and distribution agreements in India and China are deferred untilTc99m tilmanocept has been approved by the regulatory authorities in each of those countries. It is not possible to determine with any degree of certainty whether or when regulatory approval for this product will be achieved in India or China, if at all. In addition, since sales of Tc99m tilmanocept have not yet begun in India or China, there is no basis for estimating whether, to what degree, or the rate at which the product will be accepted and utilized in these markets. Therefore, it is not possible to determine with any degree of certainty the expected sales in future periods in those countries. As such, the Company intends to recognize revenue from up-front and milestone payments on a straight-line basis beginning at the time of regulatory approval in each country through the end of the initial term of each agreement. The initial term of each agreement is eight years in India and 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 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 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 does not estimate expected refunds nor do we adjust revenue downward. The Company will evaluate and update the estimated transaction prices of its contracts with customers at the end of each reporting period.

During the three-month periods ended June 30, 2021 and 2020, the Company recognized revenue from contracts with customers of approximately $13,000 and $9,000, respectively. During the six-month periods ended June 30, 2021 and 2020, the Company recognized revenue from contracts with customers of approximately $36,000 and $24,000, respectively. During the three-month and six-month periods ended June 30, 2021 and 2020, the Company did not recognize any related impairment losses, nor did the Company recognize any revenue from performance obligations associated with long-term contracts that were satisfied (or partially satisfied) in previous periods.

The following table disaggregates the Company's revenue from contracts with customers for the three-month and six-month periods ended June 30, 2021 and 2020.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Royalty revenue:				
Tc99m tilmanocept - Europe	$ —	$ 8,920	$ —	$ 24,141
License revenue:				
Tc99m tilmanocept - Europe	$ 13,063	$ —	$ 35,549	$ —

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

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

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

Through June 30, 2021, 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 condensed consolidated balance sheets, during the three-month and six-month periods ended June 30, 2021 and 2020.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Total deferred revenue, beginning of period	$ 700,000	$ 700,000	$ 700,000	$ 700,000
Revenue deferred related to sublicense	—	160,000	—	160,000
Revenue recognized from satisfaction of performance obligations	—	—	—	—
Total deferred revenue, end of period	$ 700,000	$ 860,000	$ 700,000	$ 860,000

The Company had license revenue receivable of approximately $98,000 and $59,000 outstanding as of June 30, 2021 and December 31, 2020.

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 June 30, 2021 and 2020, the Company recognized grant revenue of $73,000 and $262,000, respectively. During the six-month periods ended June 30, 2021 and 2020, the Company recognized grant revenue of $74,000 and $403,000, respectively.

On May 11, 2020 (the "Termination Date"), the Company entered into a Termination Agreement (the "Termination Agreement") with SpePharm AG ("SpePharm") and Norgine BV ("Norgine") which terminated that certain Exclusive License Agreement dated March 5, 2015 (as amended to date, the "License Agreement"). Under the License Agreement, SpePharm had the exclusive right to develop, manufacture and commercialize the Company's products approved for radiolabeling with Tc99m and containing Lymphoseek® (collectively, the "Products") in several jurisdictions abroad, including the United Kingdom, France, Germany, Australia and New Zealand (collectively, the "Licensed Territory"). In exchange for such rights, the Company was entitled to certain royalty payments.

Pursuant to the Termination Agreement, the parties agreed that neither owed the other any payments due under the License Agreement as of the Termination Date and that, among other things, SpePharm no longer has any right in, nor claim to, any intellectual property owned by the Company or its affiliates anywhere in the world. SpePharm also agreed to perform certain wind-down activities (the "Wind-Down Activities") during the six-month period following the Termination Date (the "Transition Period"), which Transition Period was extended by ninety days. The Wind-Down Activities included, without limitation, SpePharm transferring to the Company or its designee(s) the regulatory approvals controlled by SpePharm or its affiliates for the purpose of marketing, distributing and selling the Products in the Licensed Territory. SpePharm also transferred to the Company certain tenders and other customer and sales contracts related to the Products. Subject to the terms of the Termination Agreement, Norgine, an affiliate of SpePharm, agreed to guarantee SpePharm's performance of its obligations under the Termination Agreement. Although the Transition Period has elapsed, SpePharm is continuing to fulfill customer orders until the Company obtains the regulatory license required to distribute the product in Europe, which license the Company anticipates will be issued during the third quarter of 2021.

4. Stock-Based Compensation

For the three-month periods ended June 30, 2021 and 2020, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $142,000 and $35,000, respectively. For the six-month periods ended June 30, 2021 and 2020, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $263,000 and $74,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in any of the three-month or six-month periods ended June 30, 2021 and 2020.

A summary of the status of our stock options as of June 30, 2021, and changes during the six-month period then ended, is presented below.

	Six Months Ended June 30, 2021			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2021	549,970	$ 8.81	8.0	$ 209,280
Granted	232,000	2.54		
Exercised	(2,000)	1.06		
Cancelled/Forfeited	(67,600)	4.01		
Outstanding, June 30, 2021	712,370	$ 7.25	7.8	$ 143,695
Exercisable, June 30, 2021	186,638	$ 15.64	5.3	$ 52,874

The weighted average grant date fair value per stock option granted during the six-month period ended June 30, 2021 was $1.86. Key assumptions used in the Black-Scholes option pricing model for stock options granted during the six-month period ended June 30, 2021 were the Company's stock price, an expected volatility rate of 90.22%, a risk-free rate of 0.67%, and an expected life of 5.97 years.

A summary of the status of our unvested restricted stock as of June 30, 2021, and changes during the six-month period then ended, is presented below.

	Six Months Ended June 30, 2021	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested, January 1, 2021	60,000	$ 2.90
Granted	15,000	2.17
Vested	(15,000)	1.47
Unvested, June 30, 2021	60,000	$ 3.08

As of June 30, 2021, there was approximately $415,000 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 1.6 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 six-month periods ended June 30, 2021 and 2020 excludes the effects of 1,684,694 and 1,423,344 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, 60,000 and 10,000 shares of unvested restricted stock for the six-month periods ended June 30, 2021 and 2020, 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 June 30, 2021 and December 31, 2020 are as follows:

	June 30, 2021	December 31, \2020
Materials	$ 77,750	$ 77,750
Finished goods	101,080	92,048
Total inventory	$ 178,830	$ 169,798

During the three-month and six-month periods ended June 30, 2021, we allocated approximately $1,000 and $5,000, respectively, of finished goods inventory for use in clinical trials. These transactions were recorded in research and development expense in the condensed consolidated statements of operations.

7. Investment in Macrophage Therapeutics, Inc.

In August 2018, Dr. Michael Goldberg resigned from his positions as an executive officer and a director of Navidea. In connection with Dr. Goldberg's resignation, Navidea and Dr. Goldberg entered into an Agreement (the "Goldberg Agreement"), with the intent of entering into one or more additional definitive agreements, which set forth the terms of the separation from service. In February 2019, the MT Board removed Dr. Goldberg as President and Chief Executive Officer of MT and from any other office of MT to which he may have been appointed or in which he was serving. Dr. Goldberg remains a member of the MT Board, together with Michael Rice and Dr. Claudine Bruck. Dr. Bruck remains a member of the board of directors of Navidea. The MT Board then appointed Jed A. Latkin to serve as President and Chief Executive Officer of MT. On or about December 18, 2020 the Joint Official Liquidators and Foreign Representatives of Platinum Partners Value Arbitrage Fund L.P. sent a letter to MT directing that Dr. Goldberg be removed from the MT Board. The MT Board has taken no action in response. See Note 11 with respect to the litigation matters related to Dr. Goldberg in Note 7.

8. Accounts Payable, Accrued Liabilities and Other

Accounts payable as of June 30, 2021 and December 31, 2020 includes an aggregate of $28,000 and $66,000, respectively, due to related parties for director fees. Accrued liabilities and other as of June 30, 2021 and December 31, 2020 includes an aggregate of $613,000 and $755,000, respectively, due to related parties for accrued bonuses, benefits, termination costs and director fees. During the second quarter of 2021, the Company began paying director fees 50% in cash and 50% in stock. As a result, 50% of the second quarter director fees are included in accounts payable and 50% are included in accrued liabilities and other in the condensed consolidated balance sheet as of June 30, 2021.

9. Notes Payable

First Insurance Funding

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

Interest expense related to the FIF note payable totaled $2,000 and $5,000 during the three-month and six-month periods ended June 30, 2020, respectively.

IPFS Corporation

In November 2020, we prepaid $442,000 of insurance premiums through the issuance of a note payable to IPFS Corporation ("IPFS") with an interest rate of 3.5%. The note is payable in seven monthly installments of $64,000, with the final payment due in June 2021.

Interest expense related to the IPFS note payable totaled $1,000 and $4,000 during the three-month and six-month periods ended June 30, 2021, respectively. The balance of the IPFS note payable was $0 and $379,000 as of June 30, 2021 and December 31, 2020, respectively.

Paycheck Protection Program

The CARES Act was enacted on March 27, 2020. Among the provisions contained in the CARES Act was the creation of the PPP that provides for SBA loans for qualified small businesses. PPP loan proceeds are available to be used to pay for payroll costs, including salaries, commissions, and similar compensation, group health care benefits, and paid leaves; rent; utilities; and interest on certain other outstanding debt. On May 18, 2020, the Lender funded the PPP Loan to the Company in the amount of $366,000. In accordance with the loan forgiveness requirements of the CARES Act, the Company used the proceeds from the PPP Loan primarily for payroll costs, rent and utilities. On February 23, 2021, the Lender notified the Company that the entire PPP Loan amount of $366,000 has been forgiven. See Note 2.

Summary

During the three-month periods ended June 30, 2021 and 2020, we recorded interest expense of $1,000 and $2,000, respectively, related to our notes payable. During the six-month periods ended June 30, 2021 and 2020, we recorded interest expense of $4,000 and $5,000, respectively, related to our notes payable.

10. Leases

We currently lease approximately 5,000 square feet of office space at 4995 Bradenton Avenue, Dublin, Ohio, as our principal offices, at a monthly base rent of approximately $3,000. The current 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 approximately $27,000 in 2021. 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 approximately $39,000 through October 2022.

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

Total operating lease expense was $44,000 and $50,000 for the three-month periods ended June 30, 2021 and 2020, respectively. Total operating lease expense was $90,000 and $102,000 for the six-month periods ended June 30, 2021 and 2020, respectively. Operating lease expense 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 June 30, 2021.

Maturity of Lease Liabilities	Operating Lease Payments
2021 (remaining)	$ 159,131
2022	291,111
2023	19,699
2024	1,355
Total undiscounted operating lease payments	471,296
Less imputed interest	36,973
Present value of operating lease liabilities	$ 434,323
Balance Sheet Classification	
Current lease liabilities	$ 313,852
Noncurrent lease liabilities	120,471
Total operating lease liabilities	$ 434,323
Other Information	
Weighted-average remaining lease term for operating leases (years)	1.4
Weighted-average discount rate for operating leases	11.0%

Cash paid for amounts included in the present value of operating lease liabilities was $185,000 and $181,000 during the six-month periods ended June 30, 2021 and 2020, respectively, and is included in operating cash flows.

11. Commitments and Contingencies

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

CRG Litigation

As disclosed in the notes to the financial statements included in the Company's Annual Report on 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 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 had 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 Global Settlement Agreement, 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 Global Settlement Agreement 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 Global Settlement Agreement, and their double recovery of amounts paid as part of the $4.1 million paid in June 2016 and recovered again as part of the $66.0 million. CRG's double recovery and recovery of more than $66.0 million are due to CRG drawing the entire $7.1 million on the Cardinal Health 414 letter of credit. The 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 onJune 28, 2019. On November 27, 2019, the Ohio Court found that when CRG collected more than$66.0 million, they took an excess recovery and breached the Global Settlement Agreement. The Ohio Court awarded approximately $4.3 million to Navidea, plus statutory interest from April 9, 2018, the date CRG drew on the Cardinal Health 414 letter of credit. The Ohio Court also found that there wasno 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 onSeptember 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 Global Settlement Agreement 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. On April 30, 2021, Navidea filed a notice of appeal of the Ohio Court of Appeals' decision to the Ohio Supreme Court along with a memorandum in support of jurisdiction. On July 20, 2021 the Ohio Supreme Court issued an announcement declining to accept the appeal for review. The case was then returned to the Ohio Court, and, on August 5, 2021, the Company filed a notice of voluntary dismissal without prejudice of its claims in the Ohio Court. The Company is presently evaluating its options with respect to claims against CRG.

CRG filed another lawsuit in the Texas Court in April 2018. This suit seeks a declaratory judgment that CRG didnot breach the Global Settlement Agreement by drawing the entire $7.1 million on the Cardinal Health 414 letter of credit. CRG also alleges that the Company breached the Global Settlement Agreement by appealing the Texas Court's judgment and by filing the suit in Franklin County, Ohio. The Company moved to dismiss CRG's claims under the Texas Citizens' Participation Act. The Texas Court denied the motion to dismiss. The Company filed an interlocutory appeal of the denial of its motion to dismiss. The Court of Appeals affirmed the Texas Court's refusal to dismiss CRG's claim on August 28, 2020. The Company has filed a petition for review with the Texas Supreme Court seeking to reverse the Texas Court's ruling. The Texas Supreme Court denied the Company's petition on December 18, 2020, and litigation resumed in the Texas Court on February 1, 2021. CRG filed a motion for summary judgment in the Texas Court on July 1, 2021. The motion for summary judgment hasnot yet been set for hearing and it is currently unknown when it will be heard or decided. See Note 2.

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. A preliminary conference was set for April 28, 2020 but was cancelled due to the COVID-19 pandemic. After a delay due to the New York Supreme Court not accepting non-emergency filings due to the pandemic, Navidea filed a Motion to Dismiss on June 4, 2020. 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 is now docketed with the Appellate Department-First Division. Platinum-Montaur perfected its appeal on or about June 28, 2021. Briefing of the appeal has commenced but a timeline for resolution of the appeal, including potential oral argument, is unknown. See Note 2.

Goldberg Agreement and Litigation

In August 2018, Dr. Michael Goldberg resigned from his positions as an executive officer and a director of Navidea. In connection with Dr. Goldberg's resignation, Navidea and Dr. Goldberg entered into the Goldberg Agreement, with the intent of entering into one or more additional Definitive Agreements, which set forth the terms of the separation from service. Among other things, the Goldberg Agreement provided that Dr. Goldberg would be entitled to 1,175,000 shares of our Common Stock, representing in part payment of accrued bonuses and payment of the balance of the Platinum debt. A portion of the 1,175,000 shares to be issued to Dr. Goldberg 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 Michael Rice and Dr. Claudine Bruck. Dr. Bruck remains a member of the board of directors of Navidea. The MT Board then appointed Jed A. Latkin to serve as President and Chief Executive Officer of MT. On or about December 18, 2020 the Joint Official Liquidators and Foreign Representatives of Platinum Partners Value Arbitrage Fund L.P. sent a letter to MT directing that Dr. Goldberg be removed from the MT Board. The MT Board has taken no action in response.

New York Litigation Involving Dr. Goldberg

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

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

The District Court also rejected Dr. Goldberg's claim for wrongful termination as Chief Executive Officer of MT. In addition, the District Court found that Dr. Goldberg lacked standing to seek injunctive relief to force the removal of Dr. Claudine Bruck and Michael Rice from 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. The parties have briefed the issue to the District Court for resolution on how much in fees Dr. Goldberg is owed under the District Court's order.

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

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

On August 24, 2020, in connection with Dr. Goldberg's motion for advancement, the District Court adopted the Magistrate Judge's report and recommendation and found that while Dr. Goldberg was not being granted advancement of fees and expenses incurred in connection with either the Delaware Action or the assertion of third-party claims against MT, the District 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. Dr. Goldberg also asked the Court to accelerate the timeline by which advancement will occur, and to expand the scope of issues to which Dr. Goldberg would be entitled to advancement and sought to hold Navidea in contempt for failing to advance fees to date. The Company opposed Dr. Goldberg's requests.

On May 27, 2021, the District Court adopted the report and recommendation of the Magistrate Judge and ordered that: (1) Dr. Goldberg only be awarded $14,955 for indemnification for his attorneys' fees; (2) Dr. Goldberg only 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 Court's orders.

Fact discovery in the New York Action has been completed and the Court has ordered that expert discovery be completed no later than November 30, 2021.

Delaware Litigation Involving Dr. Goldberg

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

A trial on MT's claims against Goldberg for breach of fiduciary duty and conversion was held on December 1 through December 3, 2020. Following the three-day trial and extensive post-trial briefing, the Delaware Court agreed with MT that Dr. Goldberg breached his fiduciary duty. Specifically, the 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 does not 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 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.

Derivative Action Involving Dr. Goldberg

On July 26, 2019, Dr. Goldberg served shareholder demands on the Boards of Directors of Navidea and MT repeating many of the claims made in the lawsuits described above. On or about November 20, 2019, Dr. Goldberg commenced a derivative action purportedly on behalf of MT in the District Court against Dr. Claudine Bruck, Y. Michael Rice, and Jed Latkin alleging a claim for breach of fiduciary duty based on the actions alleged in the demands. On April 3, 2020, Dr. Goldberg dismissed the derivative action in New York without prejudice, and the Court approved the dismissal. Dr. Goldberg retains the ability to re-file the action in Delaware. Dr. Goldberg has not yet re-filed his derivative complaint. See Notes 2 and 7.

NYSE American Continued Listing Standards

Navidea must maintain compliance with NYSE American continued listing standards, including those relating to stockholders' equity. Specifically, Sections 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide (the "Guide"), the highest of such standards requiring an issuer to have stockholders' equity of $6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years. As of June 30, 2021, the Company had stockholders' equity of approximately $5.7 million.

Even if an issuer does not meet the standards required by Sections 1003(a)(i), (ii) and (iii) of the Guide, the NYSE American will not normally consider delisting securities of an issuer that fails to meet these requirements if the issuer has (1) average global market capitalization of at least $50,000,000; or total assets and revenue of $50,000,000 in its last fiscal year, or in two of its last three fiscal years; and (2) the issuer has at least 1,100,000 shares publicly held, a market value of publicly held shares of at least $15,000,000 and 400 round lot shareholders. As of June 30, 2021, the Company's total market capitalization was approximately $55.2 million. However, declines in the Company's stock price since June 30, 2021 have at times resulted in total market capitalization falling below $50.0 million. Therefore, we may not be able to continue meeting these exceptions and there is a risk that our Common Stock may be delisted as a result of our failure to meet the minimum stockholders' equity requirement for continued listing.

12. Equity

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

In February 2020, the Company executed agreements with two existing investors to purchase approximately 4.0 million shares of the Company's Common Stock for aggregate gross proceeds to Navidea of approximately $3.4 million. The entire $3.4 million was received and the related 4,020,588 shares of Common Stock were issued during 2020.

On August 30, 2020, the Company entered into a Common Stock Purchase Agreement with the Investors named therein, pursuant to which the Investors agreed to purchase from the Company up to $25.0 million in shares of the Company's Common Stock. As of the date of filing of this Quarterly Report on Form 10-Q, we have received only $25,000 of the $5.0 million that is currently owed under the Common Stock Purchase Agreement. In accordance with current accounting guidance, the remaining $4.975 million of stock subscriptions receivable was included in common stock subscriptions receivable in the consolidated balance sheet as of December 31, 2020. During the second quarter of 2021, the Company determined that it is unlikely that the remaining $4.975 million will ever be collected. Accordingly, the common stock subscription receivable was reversed from the condensed consolidated balance sheet as of June 30, 2021. See Note 2.

On August 31, 2020, the Company entered into a Series D Preferred Stock Purchase Agreement with Keystone pursuant to which the Company agreed to issue to Keystone 150,000 shares of Series D Preferred Stock for an aggregate purchase price of $15.0 million. Pursuant to the Series D Preferred Stock Purchase Agreement, Keystone agreed to purchase Series D Preferred Stock in amounts to be determined by Keystone in one or more closings. The Series D Preferred Stock is convertible into a maximum of 5,147,000 shares of Common Stock. Of the $15.0 million, approximately $7.25 million was received and the related 72,500 shares of Series D Preferred Stock were issued through June 30, 2021. These 72,500 shares were subsequently converted into 3,778,789 shares of Common Stock through June 30, 2021. Of the $7.25 million received through June 30, 2021, $2.925 million was received prior to the filing of our Annual Report on Form 10-K for the year ended December 31, 2020. In accordance with current accounting guidance, this $2.925 million was included in stock subscriptions receivable in the consolidated balance sheet as of December 31, 2020. See Notes 2 and 17.

On March 2, 2021, the Company entered into a Series E Preferred Stock Purchase Agreement with an existing accredited investor, John K. Scott, Jr. pursuant to which the Company issued to Mr. Scott in a private placement transaction 50,000 shares of Series E Preferred Stock for an aggregate purchase price of $5.0 million.

Under the Series E Preferred Stock Purchase Agreement, Mr. Scott was granted a right of first offer with respect to future issuances of Company securities (the "Right of First Offer"); provided, however, that in no event shall Mr. Scott have such right if the acquisition of any of such securities would result in Mr. Scott beneficially holding more than 33.33% of the Company's outstanding Common Stock on an as-converted basis, as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules thereunder (the "Share Cap"). In the event that Mr. Scott does not exercise the Right of First Offer, the Company will then be entitled to offer and sell the new securities to any third party at a price not less than, and upon terms no more favorable to the offeree than, those offered to Mr. Scott (a "Third Party Offering"). Pursuant to the Series E Preferred Stock Purchase Agreement, Mr. Scott also has the option to purchase up to 33.33% of the new securities offered in a Third-Party Offering at the same price and upon the terms available to the other purchaser(s) (the "Preemptive Right"); provided, however, that in no event may Mr. Scott acquire new Company securities in a Third-Party Offering to the extent the acquisition thereof would violate the Share Cap. The Right of First Offer and the Preemptive Right will expire upon the earlier of (i) December 31, 2021 or (ii) upon the voluntary or involuntary liquidation, dissolution, or winding up of the Company.

In connection with the private placement, the Company entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which, among other things, the Company prepared and filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-1 to register for resale the maximum number of Series E Conversion Shares (as defined below) issuable upon conversion of the Series E Preferred Stock. In the event that both (i) the number of shares of Common Stock beneficially held by Mr. Scott falls below 20% of the outstanding Common Stock on an as-converted basis, as determined in accordance with Section 13(d) of the Exchange Act and the rules thereunder, and (ii) Mr. Scott is an affiliate (as that term is defined under Rule 144) at the time of the Reload Request (as defined below), the Company, upon written request from Mr. Scott (the "Reload Request"), will be required prepare and file with the SEC one, and only one, additional registration statement covering the resale of those shares of Common Stock owned by Mr. Scott as of the date of the Reload Request that, as of such time, are not registered for resale under the Securities Act of 1933, as amended (the "Securities Act"). The securities issued in the offering have not been registered under the Securities Act, and until so registered the securities may not be offered or sold absent registration or availability of an applicable exemption from registration.

Except with respect to transactions which may adversely affect any right, preference, privilege or voting power of the Series E Preferred Stock, the Series E Preferred Stock has no voting rights. Whenever the Company's Board of Directors declares a dividend on Common Stock, each record holder of a share of Series E Preferred Stock on the record date set by the Board of Directors will be entitled to receive an amount equal to such dividend declared on one share of Common Stock multiplied by the number of shares of Common Stock (the "Series E Conversion Shares") into which such share of Series E Preferred Stock could be converted on the record date, without regard to any conversion limitations in the Series E Preferred Certificate of Designation of Preferences, Rights and Limitations (the "Series E Preferred Certificate"). Holders of the Series E Preferred Stock may convert some or all of the Series E Preferred Stock into Series E Conversion Shares at a fixed price of $2.30 per Series E Conversion Share, provided that the aggregate number of Series E Conversion Shares issued pursuant to the Series E Preferred Certificate cannot exceed the Share Cap without shareholder approval, which the Company is not required to seek. The Company has the right to redeem any outstanding shares of Series E Preferred Stock at a price of $110 per share at any time on or prior to the one-year anniversary of the issuance date, payable in cash. See Note 2.

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

During the six-month periods ended June 30, 2021 and 2020, we issued 30,018 and 32,651 shares of our common stock as matching contributions to our 401(k) Plan which were valued at $77,000 and $40,000, respectively.

During the six-month period ended June 30, 2020, we issued 94,159 shares of our common stock valued at $172,000 to our full-time employees as partial payment in lieu of cash for their 2019 bonuses.

13. Stock Warrants

As of June 30, 2021, there are 972,324 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 $17.97 per share. The warrants have remaining outstanding terms ranging from 8 months to 14.1 years.

14. Income Taxes

Income taxes are accounted for under the asset and liability method in accordance with Accounting Standards Codification 740, *Income Taxes.* Deferred tax assets ("DTAs") and deferred tax liabilities ("DTLs") are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. DTAs and DTLs are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on DTAs and DTLs of a change in tax rates is recognized in income in the period that includes the enactment date.

Current accounting standards require a valuation allowance against DTAs if, based on the weight of available evidence, it is more likely than not that some or all of the DTAs may not be realized. Due to the uncertainty surrounding the realization of these DTAs in future tax returns, all of the DTAs have been fully offset by a valuation allowance as of June 30, 2021 and December 31, 2020.

In assessing the realizability of DTAs, management considers whether it is more likely than not that some portion or all of the DTAs will not be realized. The ultimate realization of DTAs is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods) and projected future taxable income in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the DTAs are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences or tax carryforwards as of June 30, 2021.

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 June 30, 2021 or December 31, 2020 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 June 30, 2021, tax years 2017-2020 remained subject to examination by federal and state tax authorities.

As of June 30, 2021, we had approximately $153.3 million of federal and $20.1 million of state net operating loss carryforwards, as well as approximately $8.9 million of federal R&D credit carryforwards which expire from 2021 to 2040.

15. 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 June 30, 2021	**Diagnostics**	**Therapeutics**	**Corporate**	**Total**
License revenue	$ 13,063	$ —	$ —	$ 13,063
Grant and other revenue	247,983	—	—	247,983
Total revenue	261,046	—	—	261,046
Research and development expenses	1,358,123	139,933	—	1,498,056
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	873	1,411,879	1,412,752
Depreciation and amortization (2)	6,041	—	13,817	19,858
Loss from operations (3)	(1,103,118)	(140,806)	(1,425,696)	(2,669,620)
Other expense (4)	—	—	(4,420)	(4,420)
Net loss	(1,103,118)	(140,806)	(1,430,116)	(2,674,040)
Total assets, net of depreciation and amortization:				
United States	$ 269,464	$ —	$ 10,811,515	$ 11,080,979
International	199,741	—	590	200,331
Capital expenditures	—	—	2,707	2,707

Three Months Ended June 30, 2020	**Diagnostics**	**Therapeutics**	**Corporate**	**Total**
Royalty revenue	$ 8,920	$ —	$ —	$ 8,920
Grant and other revenue	215,458	46,723	—	262,181
Total revenue	224,378	46,723	—	271,101
Cost of revenue	357	—	—	357
Research and development expenses	1,193,151	88,628	—	1,281,779
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	972	1,309,363	1,310,335
Depreciation and amortization (2)	—	—	19,256	19,256
Loss from operations (3)	(969,130)	(42,877)	(1,328,619)	(2,340,626)
Other income (4)	—	—	15,007	15,007
Net loss	(969,130)	(42,877)	(1,313,612)	(2,325,619)
Total assets, net of depreciation and amortization:				
United States	$ 107,185	$ 36,483	$ 6,463,015	$ 6,606,683
Capital expenditures	—	—	1,947	1,947

Six Months Ended June 30, 2021	Diagnostics	Therapeutics	Corporate	Total
License revenue	$ 35,549	$ —	$ —	$ 35,549
Grant and other revenue	349,234	—	—	349,234
Total revenue	384,783	—	—	384,783
Research and development expenses	2,452,513	268,297	—	2,720,810
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	2,879	3,622,870	3,625,749
Depreciation and amortization (2)	12,081	—	25,525	37,606
Loss from operations (3)	(2,079,811)	(271,176)	(3,648,395)	(5,999,382)
Other income (4)	—	—	358,450	358,450
Net loss	(2,079,811)	(271,176)	(3,289,945)	(5,640,932)
Total assets, net of depreciation and amortization:				
United States	$ 269,464	$ —	$ 10,811,515	$ 11,080,979
International	199,741	—	590	200,331
Capital expenditures	—	—	2,707	2,707

Six Months Ended June 30, 2020	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 24,141	$ —	$ —	$ 24,141
Grant and other revenue	274,374	128,858	—	403,232
Total revenue	298,515	128,858	—	427,373
Cost of revenue	966	—	—	966
Research and development expenses	2,150,777	130,271	—	2,281,048
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	(550)	3,121,796	3,121,246
Depreciation and amortization (2)	—	—	36,099	36,099
Loss from operations (3)	(1,853,228)	(863)	(3,157,895)	(5,011,986)
Other income (4)	—	—	12,759	12,759
Net loss	(1,853,228)	(863)	(3,145,136)	(4,999,227)
Total assets, net of depreciation and amortization:				
United States	$ 107,185	$ 36,483	$ 6,463,015	$ 6,606,683
Capital expenditures	—	—	8,406	8,406

(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 ($19,858 and $19,256 for the three-month periods ended June 30, 2021 and 2020, and $37,606 and $36,099 for the six-month periods ended June 30, 2021 and 2020, respectively).

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

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

16. Supplemental Disclosure for Statements of Cash Flows

During the six-month periods ended June 30, 2021 and 2020, we paid interest aggregating $4,000 and $5,000, respectively. During the six-month period ended June 30, 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. In February 2020, the Company amended its existing office lease and recognized a right-of-use lease asset in exchange for a lease liability of $100,432. During the six-month periods ended June 30, 2021 and 2020, we issued 30,018 and 32,651 shares of our common stock as matching contributions to our 401(k) Plan which were valued at $77,000 and $40,000, respectively. During the six-month period ended June 30, 2020, we issued 94,159 shares of our common stock valued at $172,000 to our employees as partial payment in lieu of cash for their 2019 bonuses. During the six-month period ended June 30, 2020, 411,000 Series OO warrants to purchase the Company's common stock were exercised on a cashless basis in exchange for issuance of 300,595 shares of Navidea common stock. During the six-month period ended June 30, 2020, the Company recorded a deemed dividend of approximately $78,000 related to the BCF on 70,000 shares of Series C Preferred Stock, and 70,000 shares of Series C Preferred Stock were converted into 410,765 shares of Common Stock.

17. Subsequent Events

The Company has evaluated events and transactions subsequent to June 30, 2021 and through the date these condensed consolidated financial statements were included in this Quarterly Report on Form 10-Q and filed with the SEC.

On July 8, 2021, the Company entered into the Series D Amendment with Keystone pursuant to which Keystone agreed to purchase 22,077 shares of Series D Preferred Stock on or before July 9, 2021 at 5 p.m. Eastern Time for an aggregate purchase price of approximately $2.2 million. The Series D Amendment amended the Series D Preferred Stock Purchase Agreement dated August 31, 2020 between the parties. Prior to the Amendment Effective Date, Keystone had purchased 72,500 shares of Series D Preferred Stock pursuant to the Series D Preferred Stock Purchase Agreement, leaving a remaining balance of 77,500 shares of Series D Preferred Stock. After purchasing 22,077 of the remaining shares, Keystone has no further right or obligation to purchase shares of Series D Preferred Stock. The Series D Amendment also contains a customary mutual release provision.

The entire $2.2 million was received and the related 22,077 shares of Series D Preferred Stock were issued on July 8, 2021. In accordance with current accounting guidance, $2.2 million of stock subscriptions receivable was included in stock subscriptions and other receivables in the condensed consolidated balance sheet as of June 30, 2021. See Notes 2 and 12.

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;
- 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;
- our ability to successfully commercialize our drug candidates, including delays or disruptions related to the ongoing COVID-19 pandemic;
- 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;
- 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 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 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., 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 15 to the accompanying condensed 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 has been delayed by the impact of COVID-19 in that country.

Navidea has completed enrollment and imaging events in Arms 1, 2, and 3 of the Company's ongoing Phase 2b clinical trial (NAV3-31) and delivered interim data. In addition, the Company launched a Phase 2b clinical trial (NAV3-35) designed to accrue hand and wrist planar and SPECT/CT images from healthy subjects (with SPECT/CT imaging also done on a small group of rheumatoid arthritis ("RA") patients) so that Navidea can complete a normative database in support of its RA imaging commercial product development. The Company's pivotal Phase 3 trial for RA (NAV3-33) also remains on track for a second-half 2021 launch. The additional Phase 2b trial (NAV3-32) correlating Tc99m tilmanocept uptake in RA-involved joints with CD206 immunohistochemistry findings from synovial biopsies has received investigational review board approval at both Northwestern University and in the United Kingdom and recruitment has begun at both sites. A third site in California is scheduled to open for enrollment in August 2021. In addition, the investigator-initiated Phase 2 cardiovascular ("CV") study is nearing completion at Massachusetts General Hospital with the last subject having been recruited and imaged. 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 single photon emission computed tomography ("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 ("NASH"), 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 ("CNS") diseases, and inflammation. For the near term, we have selected target diseases that may, if successfully developed, benefit from this technology.

The Company has developed processes for producing the first two therapeutic Manocept immuno-construct series, the MAN-DOX series, which is designed to specifically target and kill or modify activated CD206+ macrophages by delivering doxorubicin, and the 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 contracted with independent facilities 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 an advanced MAN-DOX construct has been successfully evaluated in both human macrophage cell culture assays and in various syngeneic mouse models of cancer. Similar evaluations of an advanced MAN-DEX construct are currently ongoing.

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 have completed pharmacokinetic, pharmacodynamics and radiation dosimetry phases in human subjects as well. The majority of the costs of these studies have been supported through a Small Business Innovation Research ("SBIR") grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1). Results of this Phase 1/2 study were presented at the June 2018 and June 2019 SNMMI meetings, the 2018 European League Against Rheumatism ("EULAR") meeting and the 2018 ACR meeting. These studies have been combined and submitted for peer review publication and full published results will follow.

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

In April 2019, the Company received feedback from the FDA regarding the Company's planned clinical studies that will evaluate joint disease in patients with RA and monitor patient response to therapy. The Company's proposed RA studies were discussed with the FDA during an in-person meeting and through follow-up collaborative efforts. The FDA communicated that the first study, a Phase 2b trial, is aligned with expectations for the studies and that they will continue to work with Navidea as we progress into a second Phase 2b trial correlating Tc99m tilmanocept uptake in RA-involved joints with CD206 immunohistochemistry findings from synovial biopsies and into the planned Phase 3 clinical trial. In May 2019, we began enrolling patients into the first Phase 2b study, entitled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value ("TUV") on Tc99m Tilmanocept Planar Imaging" (ClinicalTrials.gov MCT03938636). This study will provide confirmatory support necessary to initiate Navidea's Phase 3 study program.

In October 2019, the Company performed its first interim analysis of this trial, covering subjects enrolling into Arms 1 and 2. The results of this interim analysis were in line with the Company's hypotheses that Tc99m tilmanocept can provide robust, stable imaging in healthy subjects as well as in patients with active RA, and provide the fundamental information needed to keep moving forward into the Phase 3. 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 mirrors 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-tumor necrosis factor ("TNF") alpha 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 now 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 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 trial dataset and resultant briefing book containing the results of this analysis in preparation for the standard End-of-Phase 2 Type B meeting, which is scheduled to take place on September 1, 2021. The pivotal Phase 3 study program will assess joint disease status and monitor patient response to therapy.

Cardiovascular Disease

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

A nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc99m tilmanocept product dosed 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 enrollment is complete, with full image analysis to come.

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 supports a research collaboration between Navidea and Dr. Suzanne Lapi of the University of Alabama Birmingham. This work has as its aim the evaluation of [68]gallium tilmanocept for imaging plaques in an animal model of atherosclerosis. Activities began in the fourth quarter of 2019.

Kaposi's Sarcoma

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

Tuberculosis ("TB")

In April 2019, we announced that Professor Mike Sathekge, MBChB, M. Med (Nuclear Medicine), PhD, Professor and Head of the Department of Nuclear Medicine in the Faculty of Health Sciences at the University of Pretoria/Steve Biko Academic Hospital, planned to initiate a comparative study evaluating the use of tilmanocept in patients with TB. The purpose of 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 Manocept doxorubicin construct significantly synergized the activity of another anticancer therapy producing anti-tumor activity that was greater than either treatment alone. Results from this study will be 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 developing Manocept constructs with different payloads is ongoing.

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 have received additional funding to continue therapeutic studies in this disease with the goal of completing an investigational new drug ("IND") submission for a Manocept construct (MAN-DOX class of compounds) consisting of tilmanocept linked to doxorubicin for the treatment of KS. The first part of the grant, now complete, supported analyses including *in vitro* and cell culture studies, to be followed by Parts 2 and 3 FDA-required preclinical animal testing studies. The information from these studies can be combined with other information in an IND application that can be submitted to the FDA requesting permission to begin testing the compound in selected KS subjects (supported by NIH/NCI 1 R44 CA206788-01).

Other Immunotherapeutic Applications

The Company continues to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on the Manocept platform, including ongoing studies in KS, RA and infectious diseases. The immuno-inflammatory process is remarkably complex and tightly regulated with indicators that initiate, maintain and shut down the process. Macrophages are immune cells that play a critical role in the initiation, maintenance, and resolution of inflammation. They are activated and deactivated in the inflammatory process. Because macrophages may promote dysregulation that accelerates or enhances disease progression, diagnostic and therapeutic interventions that target macrophages may open new avenues for controlling inflammatory diseases. There can be no assurance that further evaluation or development will be successful, that any Manocept platform product candidate will ultimately achieve regulatory approval, or if approved, the extent to which it will achieve market acceptance.

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 $2.7 million and $2.3 million in total on research and development activities during the six-month periods ended June 30, 2021 and 2020, respectively. Of the total amounts we spent on research and development during those periods, excluding costs related to our internal research and development headcount and our general and administrative staff which we do not currently allocate among the various development programs that we have underway, we incurred out-of-pocket charges by program as follows:

	Six Months Ended June 30,	
Development Program [a]	**2021**	**2020**
Manocept Platform – Diagnostics	$ 1,626,359	$ 1,296,233
Manocept Platform – Therapeutics	268,297	130,271
Tc99m Tilmanocept	14,994	13,574

(a) Certain development program expenditures were offset by grant reimbursement revenues totaling $74,000 and $403,000 during the six-month periods ended June 30, 2021 and 2020, respectively.

We expect to continue the advancement of our efforts with our Manocept platform during the remainder of 2021. We currently expect our total research and development expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be higher in 2021 than in 2020. 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 pandemic may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver clinical drug supplies on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

The extent to which the 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, if needed.

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 EU. 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, as well as related to the potential marketing registration and sale of Tc99m tilmanocept in markets other than the EU. There can be no assurance that Tc99m tilmanocept will achieve regulatory approval in any market other than the EU, or if approved in those markets, that it will achieve market acceptance in the EU or any other market.

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 June 30, 2021 and 2020

Royalty Revenue. During the second quarter of 2020, we recognized royalty revenue of $9,000 related to our license agreement with SpePharm AG ("SpePharm," an affiliate of Norgine BV) in Europe. No royalty revenue was recorded during the second quarter of 2021.

License Revenue. During the second quarter of 2021, we recognized license revenue of $13,000 related to net transitional sales from SpePharm in Europe. No license revenue was recorded during the second quarter of 2020.

Grant and Other Revenue. During the second quarters of 2021 and 2020, we recognized grant and other revenue of $248,000 and $262,000, respectively. Grant revenue of $73,000 and $262,000 during the second quarters of 2021 and 2020, respectively, was primarily related to SBIR grants from the NIH supporting Manocept development. Other revenue during the second quarter of 2021 included $100,000 from Cardinal Health 414 for reimbursement of certain research and development costs and $75,000 from LikeMinds, successor to Alseres Pharmaceuticals, Inc. ("Alseres"), for the partial recovery of debts previously written off in 2015.

Research and Development Expenses. Research and development expenses increased $216,000, or 17%, to $1.5 million during the second quarter of 2021 from $1.3 million during the same period in 2020. The increase was primarily due to net increases in drug project expenses related to (i) increased Manocept diagnostic development costs of $184,000 including increased clinical trial costs offset by decreased manufacturing-related activities and decreased license fees; and (ii) increased Manocept therapeutic development costs of $52,000 including net increased preclinical and clinical development costs; offset by (iii) decreased Tc99m tilmanocept development costs of $7,000 including decreased license fees offset by increased drug cost for use in clinical trials. The net increase in research and development expenses also included increased regulatory consulting expenses of $32,000 offset by decreased employee compensation including incentive-based awards of $33,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $103,000, or 8%, to $1.4 million during the second quarter of 2021 from $1.3 million during the same period in 2020. Increased consulting services of $148,000 related to preparing for European distribution of Tc99m tilmanocept, increased director fees of $47,000 related to additional board members, increased insurance costs of $41,000 and increased travel costs of $32,000 were offset by decreased legal and professional services of $98,000 and decreased investor relations costs of $89,000.

Other Income (Expense). Other expense, net, was $4,000 during the second quarter of 2021 compared to other income, net, of $15,000 during the same period in 2020. During the second quarters of 2021 and 2020, we recognized interest income of $2,000 and $17,000, respectively. During the second quarters of 2021 and 2020, we recognized interest expense of $1,000 and $2,000, respectively.

Six Months Ended June 30, 2021 and 2020

Royalty Revenue. During the first half of 2020, we recognized royalty revenue of $24,000 related to our license agreement with SpePharm in Europe. No royalty revenue was recorded during the first half of 2021.

License Revenue. During the first half of 2021, we recognized license revenue of $36,000 related to net transitional sales from SpePharm in Europe. No license revenue was recorded during the first half of 2020.

Grant and Other Revenue. During the first half of 2021 and 2020, we recognized grant and other revenue of $349,000 and $403,000, respectively. Grant revenue of $74,000 and $403,000 during the first half of 2021 and 2020, respectively, was primarily related to SBIR grants from the NIH supporting Manocept development. Other revenue during the first half of 2021 included $175,000 from Alseres and LikeMinds for the partial recovery of debts previously written off in 2015 and $100,000 from Cardinal Health 414 for reimbursement of certain research and development costs.

Research and Development Expenses. Research and development expenses increased $440,000, or 19%, to $2.7 million during the first half of 2021 from $2.3 million during the same period in 2020. The increase was primarily due to net increases in drug project expenses related to (i) increased Manocept diagnostic development costs of $330,000 including increased clinical trial costs offset by decreased preclinical development costs, decreased manufacturing-related activities and decreased license fees; and (ii) increased Manocept therapeutic development costs of $138,000 including net increased preclinical and clinical development costs. The net increase in research and development expenses also included increased regulatory consulting expenses of $45,000 offset by decreased employee compensation including incentive-based awards of $50,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $506,000, or 16%, to $3.7 million during the first half of 2021 from $3.2 million during the same period in 2020. Increased consulting services of $365,000 related to preparing for European distribution of Tc99m tilmanocept, increased employee compensation including incentive-based awards of $155,000, increased insurance costs of $96,000, increased director fees of $62,000 related to additional board members, increased general office expenses of $26,000, increased travel costs of $25,000 and increased European license fees of $14,000 were offset by decreased legal and professional services of $170,000 and decreased investor relations costs of $58,000.

Other Income (Expense). Other income, net, was $358,000 during the first half of 2021 compared to other income, net of $13,000 during the same period in 2020. During the first half of 2021, we recognized a gain on extinguishment of debt of $366,000 resulting from forgiveness of our PPP loan. During the first half of 2021 and 2020, we recognized interest income of $2,000 and $18,000, respectively. During the first half of 2021 and 2020, we recognized interest expense of $4,000 and $5,000, respectively.

Liquidity and Capital Resources

Cash balances increased to $7.1 million as of June 30, 2021 from $2.7 million as of December 31, 2020. The net increase was primarily due to net proceeds from issuance of preferred stock of $10.4 million, offset by cash used to fund our operations of $5.5 million, payments on notes payable of $379,000 and patent and trademark costs of $104,000.

Operating Activities. Cash used in operations was $5.5 million during the first half of 2021 compared to $3.0 million used during the same period in 2020.

Accounts and other receivables decreased to $2.4 million as of June 30, 2021 from $3.0 million as of December 31, 2020, primarily due to decreased preferred stock subscriptions of $717,000, offset by increased amounts receivable for recovery of debts previously written off of $75,000, transitional sales revenue from SpePharm of $39,000 and grant revenue of $18,000.

Inventory increased to $179,000 as of June 30, 2021 from $170,000 as of December 31, 2020, primarily due to finished goods cost adjustments offset by the allocation of finished goods for use in clinical trials.

Prepaid expenses and other current assets decreased to $350,000 as of June 30, 2021 from $701,000 as of December 31, 2020, primarily due to normal amortization of prepaid insurance.

Accounts payable decreased to $1.1 million as of June 30, 2021 from $1.2 million as of December 31, 2020. Net decreased payables due for legal and professional services, insurance, consulting related to preparing for European distribution of Tc99m tilmanocept, board fees payable in cash and regulatory consulting services were offset by increased payables due for preclinical and clinical development activities, manufacturing-related activities and investor relations costs. Accrued liabilities and other current liabilities increased to $2.6 million as of June 30, 2021 from $2.5 million as of December 31, 2020, primarily related to net increased accruals for Manocept development costs offset by decreased accruals for incentive-based compensation and legal and professional services. 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 $107,000 during the first half of 2021 compared to $124,000 used during the same period in 2020. Patent and trademark costs used $104,000 and purchases of property and equipment used $3,000 during the first half of 2021. Patent and trademark costs used $115,000 and purchases of property and equipment used $8,000 during the first half of 2020.

Financing Activities. Financing activities provided $10.0 million during the first half of 2021 compared to $3.7 million provided during the same period in 2020. The $10.0 million provided by financing activities in the first half of 2021 consisted primarily of proceeds from issuance of preferred stock of $10.5 million offset by principal payments on financed insurance premiums of $379,000 and costs of issuing preferred stock of $70,000. The $3.7 million provided by financing activities in the first half of 2020 consisted primarily of proceeds from issuance of Common Stock of $3.0 million, proceeds from issuance of preferred stock of $700,000 and proceeds from notes payable of $366,000, offset by payment of Common Stock issuance costs of $150,000 and principal payments on financed insurance premiums of $262,000.

Paycheck Protection Program Loan

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted on March 27, 2020. Among the provisions contained in the CARES Act was the creation of the Paycheck Protection Program ("PPP") that provides for Small Business Administration ("SBA") Section 7(a) loans for qualified small businesses. PPP loan proceeds are available to be used to pay for payroll costs, including salaries, commissions, and similar compensation, group health care benefits, and paid leaves; rent; utilities; and interest on certain other outstanding debt. On May 18, 2020, Fifth Third Bank (the "Lender") funded a PPP loan to the Company in the amount of $366,000 (the "PPP Loan"). In accordance with the loan forgiveness requirements of the CARES Act, the Company used the proceeds from the PPP Loan primarily for payroll costs, rent and utilities. On February 23, 2021, the Lender notified the Company that the entire PPP Loan amount of $366,000 has been forgiven. See Notes 2 and 9 to the accompanying condensed consolidated financial statements.

Private Placement

On August 30, 2020, the Company entered into a Common Stock Purchase Agreement with the Investors named therein, pursuant to which the Investors agreed to purchase from the Company up to $25.0 million in shares of the Company's Common Stock. As of the date of filing of this Quarterly Report on Form 10-Q, we have received only $25,000 of the $5.0 million that is currently owed under the Common Stock Purchase Agreement. In accordance with current accounting guidance, the remaining $4.975 million of stock subscriptions receivable was included in common stock subscriptions receivable in the consolidated balance sheet as of December 31, 2020. During the second quarter of 2021, the Company determined that it is unlikely that the remaining $4.975 million will ever be collected. Accordingly, the common stock subscription receivable was reversed from the condensed consolidated balance sheet as of June 30, 2021. We are continuing to evaluate our rights and remedies under that agreement. See Notes 2 and 12 to the accompanying condensed consolidated financial statements.

Series D Preferred Stock

On August 31, 2020, the Company entered into a Stock Purchase Agreement and Letter of Investment Intent (the "Series D Preferred Stock Purchase Agreement") with Keystone Capital Partners, LLC ("Keystone") pursuant to which the Company agreed to issue to Keystone 150,000 shares of newly-designated Series D Redeemable Convertible Preferred Stock (the "Series D Preferred Stock") for an aggregate purchase price of $15.0 million. Pursuant to the Series D Preferred Stock Purchase Agreement, Keystone agreed to purchase Series D Preferred Stock in amounts to be determined by Keystone in one or more closings before the end of the nine-month period following the date when the Company's prospectus supplement to its existing registration statement on Form S-3 was filed with the SEC. On July 8, 2021 (the "Amendment Effective Date"), the Company entered into an Amendment to Stock Purchase Agreement and Letter of Investment Intent (the "Series D Amendment") with Keystone pursuant to which Keystone purchased 22,077 shares of Series D Preferred Stock for an aggregate purchase price of approximately $2.2 million. Prior to the Amendment Effective Date, Keystone had purchased 72,500 shares of Series D Preferred Stock pursuant to the Series D Preferred Stock Purchase Agreement, leaving a remaining balance of 77,500 shares of Series D Preferred Stock. After purchasing the 22,077 remaining shares, Keystone has no further right or obligation to purchase shares of Series D Preferred Stock. The Series D Preferred Stock is convertible into a maximum of 5,147,000 shares of Common Stock. See Notes 2, 12 and 17 to the accompanying condensed consolidated financial statements.

Series E Preferred Stock

On March 2, 2021, the Company entered into a Stock Purchase Agreement and Letter of Investment Intent with an existing accredited investor, John K. Scott, Jr., pursuant to which the Company issued to Mr. Scott in a private placement transaction 50,000 shares of newly-designated Series E Redeemable Convertible Preferred Stock (the "Series E Preferred Stock") for an aggregate purchase price of $5.0 million. The Series E Preferred Stock is convertible into a maximum of 2,173,913 shares of Common Stock. See Notes 2 and 12 to the accompanying condensed consolidated financial statements.

CRG Litigation

See Notes 2 and 11 to the accompanying condensed consolidated financial statements.

Platinum Litigation

See Notes 2 and 11 to the accompanying condensed consolidated financial statements.

Goldberg Agreement and Litigation

See Notes 2, 7 and 11 to the accompanying condensed consolidated financial statements.

Summary

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

We plan to focus our resources during the remainder of 2021 primarily on development of products based on the Manocept platform. Although management believes that it will be able to achieve this objective, it is subject to a number of variables beyond our control, including the nature and timing of any partnering opportunities, the ability to modify contractual commitments made in connection with these programs, and the timing and expense associated with suspension or alteration of clinical trials, and consequently we may need to seek additional financing in order to support our planned development programs.

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

The Company is currently engaged in litigation with Dr. Goldberg, CRG and Platinum-Montaur. In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. The Company has considerable discretion over the extent of development project expenditures and has the ability to curtail the related cash flows as needed. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of funding, including collaborations, potential equity investments, and additional grant funding that can augment the balance sheet. However, the 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, if needed. 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 2021 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 has funds remaining under outstanding grant awards, and continues working to establish new sources of funding, including collaborations, potential equity investments, and additional grant funding that can augment the balance sheet. However, based on our current working capital and our projected cash burn, management believes that there is substantial doubt about the Company's ability to continue as a going concern for a period of one year from the filing of this Quarterly Report on Form 10-Q. No adjustments have been made to the accompanying condensed consolidated financial statements as a result of this uncertainty. See Note 2 to the accompanying condensed consolidated financial statements.

Off-Balance Sheet Arrangements

As of June 30, 2021, we had no off-balance sheet arrangements.

Recent Accounting Standards

See Notes 1(f) and 1(g) to the accompanying condensed consolidated financial statements for a summary of all recent accounting standards.

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

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

Research and Development. 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 C, Series D and Series E Convertible Preferred Stock. The Company evaluated the provisions of the Series C, 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 C, 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 C, 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 C, Series D or Series E Preferred stock and thus these features should not be bifurcated and accounted for as derivatives. Additionally, the Series C and Series D Preferred Stock contain a beneficial conversion feature ("BCF"). Prior to the adoption of Accounting Standards Update ("ASU") No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, effective January 1, 2021, the BCF resulted in an increase to additional paid-in capital and a discount on the Series C and Series D Preferred Stock. The discounts on the Series C and Series D Preferred Stock were considered to be fully amortized at the date of issuance because the Series C and Series D Preferred Stock are immediately convertible, resulting in a deemed dividend at the date of issuance for the amount of the BCF. Finally, the Company determined that the conversion features of the Series C Preferred Stock could result in the Company being required to redeem a portion of the shares converted, thus the Series C Preferred Stock should be classified in mezzanine equity. Conversely, 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. Specifically, management may make significant estimates in the following areas:

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

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

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

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 Mr. Latkin, who serves as our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of June 30, 2021, and concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report to ensure that information required to be disclosed by us in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

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

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

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

Changes in Control Over Financial Reporting

During the quarter ended June 30, 2021, 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 11 to the accompanying condensed consolidated financial statements.

Item 1A. Risk Factors

There have been no material changes to the Company's risk factors as previously reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 26, 2021, except as described below.

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

Our Common Stock has been listed on the NYSE American exchange since February 2011. The rules of NYSE American provide that shares be delisted from trading in the event the financial condition and/or operating results of the Company appear to be unsatisfactory, the extent of public distribution or the aggregate market value of the Common Stock has become so reduced as to make further dealings on the NYSE American inadvisable, the Company has sold or otherwise disposed of its principal operating assets, or has ceased to be an operating company, or the Company has failed to comply with its listing agreements with the NYSE American. For example, the NYSE American may consider suspending trading in, or removing the listing of, securities of an issuer that has stockholders' equity of less than (i) $2.0 million if such issuer has sustained losses from continuing operations and/or net losses in two of its three most recent fiscal years, (ii) $4.0 million if such issuer has sustained losses from continuing operations and/or net losses in three of its four most recent fiscal years, and (iii) $6.0 million if such issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. As of June 30, 2021, Navidea had stockholders' equity of approximately $5.7 million. In addition, the Company had stockholders' deficits for several years prior to December 31, 2020, and we may not be able to maintain stockholders' equity in the future. Even if an issuer has a stockholders' deficit, the NYSE American will not normally consider delisting securities of an issuer that fails to meet these requirements if the issuer has (1) average global market capitalization of at least $50,000,000; or total assets and revenue of $50,000,000 in its last fiscal year, or in two of its last three fiscal years; and (2) the issuer has at least 1,100,000 shares publicly held, a market value of publicly held shares of at least $15,000,000 and 400 round lot shareholders. As of August 6, 2021, the Company's total value of market capitalization was approximately $51.3 million. We may not be able to continue meeting these exceptions and there is a risk that our Common Stock may be delisted as a result of our failure to meet the minimum stockholders' equity requirement for continued listing.

The delisting of our Common Stock from the NYSE American likely would reduce the trading volume and liquidity in our Common Stock and may lead to decreases in the trading price of our Common Stock. The delisting of our Common Stock may also materially impair our stockholders' ability to buy and sell shares of our Common Stock. In addition, the delisting of our Common Stock could significantly impair our ability to raise capital.

Item 6. Exhibits

31.1	Certification of Chief Executive 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.**
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)
August 12, 2021

By: */s/ Jed A. Latkin*

Jed A. Latkin
Chief Executive Officer, Chief Operating Officer and
Chief Financial Officer
(Authorized Officer; Principal Executive, Financial and Accounting Officer)

Exhibit 31.1

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

I, Jed A. Latkin, certify that:

1. I have reviewed this 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. I am 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. 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.

August 12, 2021

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

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

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

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

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

August 12, 2021

/s/ Jed A. Latkin
Jed A. Latkin
Chief Executive Officer, Chief Operating Officer and
Chief Financial Officer
(Principal Executive, Financial and Accounting Officer)