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

FORM 10-Q

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

For the quarterly period ended March 31, 2020

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

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 ☒

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 the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 21,645,425 shares of common stock, par value $.001 per share (as of the close of business on May 1, 2020).

NAVIDEA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Navidea Biopharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 601,355	$ 1,047,159
Accounts and other receivables	1,695,422	901,339
Prepaid expenses and other	1,149,982	967,285
Total current assets	3,446,759	2,915,783
Property and equipment	1,213,996	1,207,537
Less accumulated depreciation and amortization	1,186,041	1,177,327
Property and equipment, net	27,955	30,210
Right-of-use lease assets	458,280	404,594
Less accumulated amortization	118,223	122,906
Right-of-use lease assets, net	340,057	281,688
License agreements, patents and trademarks	536,656	478,672
Less accumulated amortization	101,388	93,259
License agreements, patents and trademarks, net	435,268	385,413
Other assets	227,192	537,812
Total assets	$ 4,477,231	$ 4,150,906
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,454,283	$ 1,112,069
Accrued liabilities and other	2,456,346	2,150,974
Notes payable	175,919	305,955
Lease liabilities, current	268,021	250,553
Total current liabilities	4,354,569	3,819,551
Lease liabilities	513,701	512,344
Deferred revenue	700,000	700,000
Total liabilities	5,568,270	5,031,895
Commitments and contingencies (Note 10)		
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at March 31, 2020 and December 31, 2019	—	—
Common stock; $.001 par value; 300,000,000 shares authorized; 21,194,248 and 19,234,960 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	212,191	210,232
Common stock subscribed; $.001 par value, 3,020,587 and 902,162 shares subscribed at March 31, 2020 and December 31, 2019, respectively	3,021	902
Common stock subscriptions receivable	(912,500)	—
Additional paid-in capital	349,219,656	345,847,676
Accumulated deficit	(350,344,712)	(347,671,102)
Total Navidea stockholders' deficit	(1,822,344)	(1,612,292)
Noncontrolling interest	731,305	731,303
Total stockholders' deficit	(1,091,039)	(880,989)
Total liabilities and stockholders' deficit	$ 4,477,231	$ 4,150,906

See accompanying notes to consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	**2019**
Revenue:		
Royalty revenue	$ 15,221	$ 3,150
Grant and other revenue	141,051	38,474
Total revenue	156,272	41,624
Cost of revenue	609	6,126
Gross profit	155,663	35,498
Operating expenses:		
Research and development	999,269	740,583
Selling, general and administrative	1,827,754	1,728,516
Total operating expenses	2,827,023	2,469,099
Loss from operations	(2,671,360)	(2,433,601)
Other income (expense):		
Interest (expense) income, net	(2,372)	9,848
Other, net	124	(1,135)
Total other income (expense), net	(2,248)	8,713
Loss before income taxes	(2,673,608)	(2,424,888)
Provision for income taxes	—	(876)
Net loss from continuing operations	(2,673,608)	(2,425,764)
Loss from discontinued operations, net of tax effect	—	(3,297)
Net loss	(2,673,608)	(2,429,061)
Income (loss) attributable to noncontrolling interest	2	(12)
Net loss attributable to common stockholders	$ (2,673,610)	$ (2,429,049)
Loss per common share (basic and diluted):		
Continuing operations	$ (0.13)	$ (0.24)
Attributable to common stockholders	$ (0.13)	$ (0.24)
Weighted average shares outstanding	20,203,636	10,017,848

See accompanying notes to consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	**2019**
Net loss	$ (2,673,608)	$ (2,429,061)
Unrealized gain on available-for-sale securities	—	958
Comprehensive loss	$ (2,673,608)	$ (2,428,103)

See accompanying notes to consolidated financial statements.

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

For the Three Months Ended March 31, 20 20

	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					
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 costs	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
Comprehensive loss:									
Net loss	—	—	—	—	—	—	(2,673,610)	2	(2,673,608)
Total comprehensive loss	—	—	—	—	—	—	—	—	(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)

For the Three Months Ended March 31, 2019

	Common Stock		Common Stock Subscribed		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Compre-hensive Loss	Non-controlling Interest	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance, January 1, 2019	10,019,535	$ 200,391	—	$ —	$ 338,265,383	$ (336,722,905)	$ (730)	$ 668,321	$ 2,410,460
Issued restricted stock	15,000	300	—	—	—	—	—	—	300
Issued stock pursuant to Stock Purchase Agreement	17,857	357	—	—	49,643	—	—	—	50,000
Stock compensation expense	—	—	—	—	61,978	—	—	—	61,978
Comprehensive loss:									
Net loss	—	—	—	—	—	(2,429,049)	—	(12)	(2,429,061)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	958	—	958
Total comprehensive loss	—	—	—	—	—	—	—	—	(2,428,103)
Balance, March 31, 2019	10,052,392	$ 201,048	—	$ —	$ 338,377,004	$ (339,151,954)	$ 228	$ 668,309	$ 94,635

See accompanying notes to consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (2,673,608)	$ (2,429,061)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	16,843	36,779
Stock compensation expense	39,246	61,978
Value of stock issued in payment of employee bonuses	64,511	—
Value of stock issued in payment of services	4,801	—
Changes in operating assets and liabilities:		
Accounts and other receivables	860,917	11,283
Prepaid expenses, right-of-use lease assets, and other assets	69,554	(217,651)
Accounts payable	342,214	427,894
Accrued, lease and other liabilities	324,197	(56,560)
Net cash used in operating activities	(951,324)	(2,165,338)
Cash flows from investing activities:		
Maturities of available-for-sale securities	—	200,000
(Payments for purchases) proceeds from disposal of equipment	(6,459)	26,875
Patent and trademark costs	(57,984)	—
Net cash (used in) provided by investing activities	(64,444)	226,875
Cash flows from financing activities:		
Proceeds from issuance of common stock	850,000	50,300
Payment of common stock issuance costs	(150,000)	—
Principal payments on notes payable	(130,036)	(117,276)
Net cash provided by (used in) financing activities	569,964	(66,976)
Net decrease in cash and cash equivalents	(445,804)	(2,005,439)
Cash and cash equivalents, beginning of period	1,047,159	3,475,881
Cash and cash equivalents, end of period	$ 601,355	$ 1,470,442

See accompanying notes to consolidated financial statements.

Notes to the Consolidated Financial Statements (unaudited)

1. Summary of Significant Accounting Policies

a. Basis of Presentation: The information presented as of March 31, 2020 and for the three-month periods ended March 31, 2020 and 2019 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. The balances as of March 31, 2020 and the results for the interim periods are not necessarily indicative of results to be expected for the year. The consolidated financial statements should be read in conjunction with Navidea's audited consolidated financial statements for the year ended December 31, 2019, which were included as part of our Annual Report on Form 10-K.

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

In March 2020, the World Health Organization categorized the current COVID-19 outbreak as a pandemic, and the President of the United States declared the COVID-19 outbreak a national emergency. COVID-19 continues to spread globally, including throughout the United States, which has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities and our supply chain. To date, we do not believe there has been any appreciable impact to the Company's clinical development and regulatory timelines resulting from COVID-19. However, 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. To date, much of the funding from the February 2020 transactions described in Note 2 below has been delayed, due in part to the COVID-19 pandemic and its devastating impact on global financial markets. The extent to which COVID-19 impacts our operations and financial results will depend on numerous evolving factors that we are not able to accurately predict, including: the duration and scope of the pandemic, government actions taken in response to the pandemic, and the impact on our ability to continue to conduct our clinical trials.

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, accounts and other receivables, and accounts payable:* The carrying amounts approximate fair value because of the short maturity of these instruments.

(2) *Notes payable:* The carrying value of our debt at March 31, 2020 and December 31, 2019 primarily consisted of the face amount of the notes plus accrued interest. At March 31, 2020 and December 31, 2019, the fair value of our notes payable was approximately $176,000 and $306,000, both amounts equal to the carrying value of the notes payable. See Note 8.

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

We also earn revenues related to our licensing and distribution agreements. The consideration we are eligible to receive under our licensing and distribution agreements typically includes upfront payments, reimbursement for research and development costs, milestone payments, and royalties. Each licensing and distribution agreement is unique and requires separate assessment in accordance with current accounting standards. See Note 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 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 as identified for purposes of compensation analysis. Short-term operating leases which have an initial term of 12 months or less are not recorded on the consolidated balance sheets. Lease expense for operating leases is recognized on a straight-line basis over the lease term. Lease expense is included in selling, general and administrative expenses on our consolidated statements of operations. See Note 9.

e. Recently Adopted Accounting Standards: In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ASU 2018-13 is intended to improve the effectiveness of disclosure requirements on fair value measurements in Topic 820. ASU 2018-13 modifies certain disclosure requirements and is effective for annual and interim reporting periods beginning after December 15, 2019. The adoption of ASU 2018-13 did not have any impact on our consolidated financial statements or our fair value disclosures.

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

2. Liquidity

As disclosed in the Company's Annual Report on Form 10-K and other filings, 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 10.

In addition, the Company is engaged in ongoing litigation with our former President and Chief Executive Officer, Dr. Michael Goldberg. See Notes 6 and 10.

The Company has also been engaged in ongoing litigation with Capital Royalty Partners II L.P. ("CRG") and pursuing recovery of approximately $4.3 million and other damages. On November 27, 2019, the Court of Common Pleas of Franklin County, Ohio (the "Ohio Court") entered a judgment in the amount of $4.3 million to Navidea, plus statutory interest from April 9, 2018 (the "Judgment"). See Note 10.

In February 2020, the Company executed a binding term sheet to sell the Judgment for $4.2 million of proceeds to Navidea. On May 6, 2020, the Company entered into a Stock Purchase Agreement and Letter of Investment Intent with Keystone Capital Partners, LLC ("Keystone") pursuant to which the Company agreed to issue to Keystone 420,000 shares of newly-designated Series C Preferred Stock for an aggregate purchase price of $4.2 million. The Series C Preferred Stock will be guaranteed by a portion of the proceeds of the Judgment. See Note 16(b).

In December 2019, the Company executed a Stock Purchase Agreement with the investors named therein. Pursuant to the Stock Purchase Agreement, the investors agreed to purchase approximately 2.1 million shares of the Company's Common Stock in a private placement for aggregate gross proceeds to the Company of approximately $1.9 million. Of this amount, approximately $1.1 million was received during 2019, resulting in approximately $812,000 of stock subscriptions receivable as of December 31, 2019. The remaining $812,000 of proceeds were received and the related Common Stock was issued in January 2020. See Note 11.

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. Of this amount, approximately $850,000 was received during the first quarter of 2020. An additional $1.7 million was received and the related Common Stock was issued during the second quarter of 2020 through the date of filing this Quarterly Report on Form 10-Q. As a result, the Company recorded approximately $1.7 million of stock subscriptions receivable as of March 31, 2020. The remaining $913,000 of proceeds have not been received as of the date of filing this Quarterly Report on Form 10-Q. See Notes 11 and 16(a).

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

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 is the creation of the Payroll 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. The amount that will be forgiven will be calculated in part with reference to the Company's full-time headcount during the eight-week period following the funding of the PPP loan. On April 30, 2020, the Company was informed by its lender, Fifth Third Bank (the "Lender"), that the Lender received approval from the SBA to fund the Company's request for a loan under the SBA's PPP (the "PPP Loan"). Per the terms of the PPP Loan, the Company will receive total proceeds of $366,000 from the Lender. In accordance with the loan forgiveness requirements of the CARES Act, the Company intends to use the proceeds from the PPP Loan primarily for payroll costs, rent and utilities, thus the Company anticipates that 100% of the loan will be forgiven. See Note 16(d).

During the ongoing COVID-19 global pandemic, the Company's primary focus 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. To date, we do not believe there has been any appreciable impact to the Company's clinical development and regulatory timelines resulting from COVID-19. However, much of the funding from the February 2020 transactions described above has been delayed, due in part to the COVID-19 pandemic and its devastating impact on global financial markets. The Company is working closely with the parties to these transactions to complete the funding as soon as possible.

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 February 2020 transactions described above have provided approximately $2.5 million of additional working capital, with another $5.1 million to be received in the future. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of funding, including collaborations, potential equity investments, and additional grant funding that can augment the balance sheet. However, based on our current working capital and our projected cash burn, and without definitive agreements in place for additional funding, management believes that there is substantial doubt about the Company's ability to continue as a going concern for at least twelve months following the filing of this Quarterly Report on Form 10-Q.

3. Revenue from Contracts with Customers

Navidea is focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. We manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform, and (ii) therapeutic development programs, including all therapeutic applications of our Manocept platform. Tc99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, is the only one of the Company's drug product candidates that has been approved for sale in any market. The Company has license and distribution agreements in place in India and China, however Tc99 tilmanocept has not been approved in either of those markets. On May 11, 2020, the Company terminated its license and distribution agreement in Europe, which is the only market in which Tc99m tilmanocept has been approved. See Note 16(c).

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 of NAV4694 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 until Tc99m tilmanocept has been approved by the regulatory authorities in each of those countries. It is not possible to determine with any degree of certainty whether or when regulatory approval for this product will be achieved in India or China, if at all. In addition, since sales of Tc99m tilmanocept have not yet begun in India or China, there is no basis for estimating whether, to what degree, or the rate at which the product will be accepted and utilized in these markets. Therefore, it is not possible to determine with any degree of certainty the expected sales in future periods in those countries. As such, the Company intends to recognize revenue from up-front and milestone payments on a straight-line basis beginning at the time of regulatory approval in each country through the end of the initial term of each agreement. The initial term of each agreement is eight years in India and ten years in China.

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

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

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

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

The sublicense of NAV4694 to Meilleur provides for payments to Navidea including up-front payments, milestones, an option for worldwide commercial rights, royalties on net sales, and reimbursement for product development assistance during the initial transition period. In accordance with 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 ASC 606 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 March 31, 2020 and 2019, the Company recognized revenue from contracts with customers of approximately $15,000 and $14,000. During the three-month periods ended March 31, 2020 and 2019, the Company did not recognize any related impairment losses, nor did the Company recognize any revenue from performance obligations associated with long-term contracts that were satisfied (or partially satisfied) in previous periods.

The following tables disaggregate the Company's revenue from contracts with customers for the three-month periods ended March 31, 2020 and 2019.

Three Months Ended March 31, 2020	**Diagnostics**
Royalty revenue:	
Europe	$ 15,221

Three Months Ended March 31, 2019	**Diagnostics**
Royalty revenue:	
Europe	$ 3,150
Other revenue:	
Additional stability studies	$ 11,024

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 have been lower than rates in India but higher than in China.

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

Through March 31, 2020, the Company has not capitalized any contract-related costs as contract assets.

The following table summarizes the changes in contract liabilities, the current portion of which is included in accrued liabilities and other in the consolidated balance sheets, during the three-month periods ended March 31, 2020 and 2019.

	Three Months Ended March 31,	
	2020	**2019**
Total deferred revenue, beginning of period	$ 700,000	$ 711,024
Revenue recognized from satisfaction of performance obligations	—	(11,024)
Total deferred revenue, end of period	$ 700,000	$ 700,000

The Company had trade receivables of approximately $0 outstanding as of March 31, 2020 and December 31, 2019.

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. ASC 606 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 and the NIH do not have a vendor-customer relationship and the grant awards are outside the scope of ASC 606. Accordingly, ASC 606 need not be applied to NIH grants.

4. Stock-Based Compensation

For the three-month periods ended March 31, 2020 and 2019, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $39,000 and $62,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2020 and 2019.

A summary of the status of our stock options as of March 31, 2020, and changes during the three-month period then ended, is presented below.

	Three Months Ended March 31, 2020			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at beginning of period	238,470	$ 17.38	7.2	$ —
Granted	195,000	1.06		
Exercised	—	—		
Canceled and Forfeited	(1,500)	1.06		
Expired	(500)	30.80		
Outstanding at end of period	431,470	$ 10.04	8.3	$ —
Exercisable at end of period	112,290	$ 25.54	5.7	$ —

A summary of the status of our unvested restricted stock as of March 31, 2020, and changes during the three-month period then ended, is presented below.

	Three Months Ended March 31, 2020	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	15,000	$ 2.75
Granted	10,000	1.06
Vested	(15,000)	2.75
Forfeited	—	—
Unvested at end of period	10,000	$ 1.06

As of March 31, 2020, there was approximately $144,000 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 debt, convertible preferred stock, options and warrants.

Diluted loss per common share for the three-month periods ended March 31, 2020 and 2019 excludes the effects of 1,515,164 and 902,050 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, 10,000 and 15,000 shares of unvested restricted stock for the three-month periods ended March 31, 2020 and 2019, respectively, were excluded in determining basic and diluted loss per share from continuing operations because such inclusion would be anti-dilutive.

6. 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.

New York Litigation Involving Dr. Goldberg

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

On December 26, 2019, the District Court ruled on several motions related to the Company and MT and Dr. Goldberg that substantially limited the claims that Dr. Goldberg can pursue against the Company and MT. Specifically, the Court found that certain portions of Dr. Goldberg's counterclaims against the Company and third-party claims against Macrophage failed to state a claim upon which relief can be granted. Specifically, the Court ruled that actions taken by the Company and MT, including reconstituting the MT Board, replacing Dr. Goldberg with Jed A. Latkin as Chief Executive Officer of MT, terminating the sublicense between the Company and MT, terminating certain research projects, and allowing MT intellectual property to revert back to the Company, were not breaches of an August 2018 Agreement between the Company, MT and Dr. Goldberg.

The Court also rejected Dr. Goldberg's claim for wrongful termination as Chief Executive Officer of MT. In addition, the 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 the Company to the Board of MT), or to reinstate the terminated sublicense between the Company and MT.

In addition, the District Court found the Company's breach of fiduciary duty claim against Dr. Goldberg for conduct occurring more than three years prior to the filing of the complaint to be time-barred and that Dr. Goldberg is entitled to an advancement of attorneys' fees solely with respect to that claim. The parties are in the process of submitting the issue to the District Court for resolution on how much in fees Dr. Goldberg is owed under the District Court's order.

On January 27, 2020, Dr. Goldberg filed a motion seeking additional advancement from Navidea for fees in connection with the New York Action and the Delaware Action. Navidea has opposed the motion.

On January 31, 2020, Dr. 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. The discovery deadline in the New York Action is June 15, 2020.

Delaware Litigation Involving Dr. Goldberg

On February 20, 2019, MT initiated a suit against Dr. Goldberg in the Court of Chancery of the State of Delaware (the "Delaware Court"), alleging, among other things, breach of fiduciary duty as a director and officer of MT and conversion, and to obtain a declaratory judgment that the transactions Dr. Goldberg caused MT to effect are void. On June 12, 2019, the Delaware Court found that Dr. Goldberg's actions were not authorized in compliance with the Delaware General Corporate Law. Specifically, the Delaware Court found that Dr. Goldberg's creation of a new subsidiary of MT and the purported assignment by Dr. Goldberg of MT's intellectual property to that subsidiary were void. The Delaware Court's ruling follows the order on May 23, 2019 in the case, in which it found Dr. Goldberg in contempt of its prior order holding Dr. Goldberg responsible for the payment of MT's fees and costs to cure the damages caused by Dr. Goldberg's contempt. MT's claims for breach of fiduciary duty and conversion against Dr. Goldberg remain pending. As a result of the Delaware Court's ruling and Navidea's prior termination of the sublicense between itself and MT, all of the intellectual property related to the Manocept platform is now directly controlled by Navidea. A trial on MT's claims against Goldberg for breach of fiduciary duty and conversion is presently scheduled for June 2020. However, due to COVID-19 impacts on the judicial system, the Company expects that the trial date will be adjourned to a future date.

Derivative Action Involving Dr. Goldberg

On July 26, 2019, Dr. Goldberg served shareholder demands on the Boards of Navidea and MT repeating many of the claims made in the lawsuits described above. On or about November 20, 2019, Dr. Goldberg commenced a derivative action purportedly on behalf of MT in the District Court against Dr. Claudine Bruck, Y. Michael Rice, and Jed Latkin alleging a claim for breach of fiduciary duty based on the actions alleged in the demands. On April 3, 2020, Dr. Goldberg dismissed the derivative action in New York without prejudice and retains the ability to re-file the action in Delaware. See Notes 2 and 10.

7. Accounts Payable, Accrued Liabilities and Other

Accounts payable at March 31, 2020 and December 31, 2019 includes an aggregate of $65,000 in both periods due to related parties for director fees. Accrued liabilities and other at March 31, 2020 and December 31, 2019 includes an aggregate of $914,000 and $925,000, respectively, due to related parties for accrued termination costs and bonuses.

8. Notes Payable

IPFS Corporation

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

Interest expense related to the IPFS note payable totaled $4,000 during the three-month period ended March 31, 2019.

First Insurance Funding

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

Interest expense related to the FIF note payable totaled $3,000 during the three-month period ended March 31, 2020. The balance of the FIF note was approximately $176,000 and $306,000 as of March 31, 2020 and December 31, 2019, respectively, and was included in notes payable, current in the consolidated balance sheets.

Summary

During the three-month periods ended March 31, 2020 and 2019, we recorded interest expense of $3,000 and $4,000, respectively, related to our notes payable.

9. Leases

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

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

In addition, we currently lease approximately 25,000 square feet of office space at 5600 Blazer Parkway, Dublin, Ohio, formerly our principal offices, at a monthly base rent of approximately $27,000 in 2020. The current lease term expires in October 2022 with an option to extend for an additional five years. The Company does not intend to renew this lease. In June 2017, the Company executed a sublease arrangement for the Blazer space, providing for monthly sublease payments to Navidea of approximately $39,000 through October 2022.

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

Total operating lease expense was $51,000 and $66,000 for the three-month periods ended March 31, 2020 and 2019, respectively, and was recorded in selling, general and administrative expenses.

The following table presents information about the amount, timing and uncertainty of cash flows arising from the Company's operating leases as of March 31, 2020.

Maturity of Lease Liabilities	Operating Lease Payments
2020 (remaining)	$ 248,003
2021	344,552
2022	291,111
2023	19,699
2024	1,355
Total undiscounted operating lease payments	904,720
Less imputed interest	122,998
Present value of operating lease liabilities	$ 781,722
Balance Sheet Classification	
Current lease liabilities	$ 268,021
Noncurrent lease liabilities	513,701
Total operating lease liabilities	$ 781,722
Other Information	
Weighted-average remaining lease term for operating leases (years)	2.6
Weighted-average discount rate for operating leases	10.9%

Cash paid for amounts included in the present value of operating lease liabilities was $91,000 and $97,000 during the three-month periods ended March 31, 2020 and 2019, respectively, and is included in operating cash flows.

10. Commitments and Contingencies

We are subject to legal proceedings and claims that arise in the ordinary course of business. 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 Company's Annual Report on Form 10-K and other filings, 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 "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. The Texas Court acknowledged only the $59.0 million payment made in March 2017, concluding that the Company owed CRG another $7.0 million, however the Texas Court did not expressly take the Company's June 2016 payment of $4.1 million into account and awarded, as part of the $66.0 million, amounts that had already been paid as part of the $4.1 million. The Company believes that this $4.1 million should be credited against the $7.0 million and has appealed the Texas Court's judgment. The Court of Appeals dismissed the Company's appeal without reaching the merits due to a contractual waiver of appeal.

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

The Company has also been engaged in ongoing litigation with CRG in the Court of Common Pleas of Franklin County, Ohio related to Navidea's claims that the Lenders fraudulently induced Navidea to enter into a settlement agreement and breached the terms of the same through certain actions taken by the Lenders in connection with the Global Settlement Agreement reached in 2017, pursuant to which Navidea agreed to pay up to $66.0 million to Lenders, as well as through actions and misrepresentations by CRG after the Global Settlement Agreement was executed. The claims in that suit are for breach of contract, conversion and unjust enrichment against the Lenders for their collection of more than $66.0 million, the maximum permitted under the Global Settlement Agreement, and their double recovery of amounts paid as part of the $4.1 million paid in June 2016 and recovered again as part of the $66.0 million. CRG's double recovery and recovery of more than $66.0 million are due to CRG drawing the entire $7.1 million on the Cardinal Health 414 letter of credit. The Lenders sought a Writ of Prohibition in the Ohio Supreme Court to prevent this case from moving forward, which was denied, and proceedings resumed in front of the Ohio Court. Following an unsuccessful mediation on May 7, 2019, Navidea moved for summary judgment on June 28, 2019. On November 27, 2019, the Ohio Court found that when CRG collected more than $66.0 million, they took an excess recovery and breached the Global Settlement Agreement. The Ohio Court awarded approximately $4.3 million to Navidea, plus statutory interest from April 9, 2018, the date CRG drew on the Cardinal Health 414 letter of credit. The Ohio Court also found that there was no unjust enrichment or conversion by CRG since this was a matter of contract and only contract damages were appropriate. The decision is a final appealable order and terminates the case 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. Oral argument may be held on the appeal, but if and when the oral argument will be held is uncertain due to the disruption caused by the COVID-19 pandemic. At present, it is unknown how long the disruptions due to the pandemic emergency will last, and thus uncertain as to the timeline under which the matter will progress in the Ohio Court of Appeals.

CRG filed another lawsuit in the Texas Court in April 2018. This suit seeks a declaratory judgment that CRG did not breach the Global Settlement Agreement by drawing the entire $7.1 million on the Cardinal Health 414 letter of Credit. CRG also alleges that the Company breached the Global Settlement Agreement by appealing the Texas Court's judgment and by filing the suit in Franklin County, Ohio. The Company moved to dismiss CRG's claims under the Texas Citizens' Participation Act. The Texas Court denied the motion to dismiss. The Company filed an interlocutory appeal of the denial of its motion to dismiss. That appeal is fully briefed, and the parties await the court of appeals' ruling. Proceedings in the Texas Court are stayed pending resolution of that appeal. See 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 (the "District Court"). On October 31, 2018, the District Court granted judgment for Navidea and dismissed all claims in the case. The District Court stated that Platinum-Montaur had no standing to assert any contractual interest in funds that might be due under the Platinum Loan Agreement. The District Court also disagreed with Platinum-Montaur's claim of unjust enrichment on similar grounds and found that Platinum-Montaur lacked any sufficient personal stake to maintain claims against Navidea. The claims against Navidea were dismissed without prejudice on the grounds of lack of standing to pursue the claims asserted.

On November 30, 2018, Platinum-Montaur filed a notice of appeal with the United States Court of Appeals for the Second Circuit (the "Second Circuit") claiming that the District Court erred in dismissing Platinum-Montaur's claims for breach of contract and unjust enrichment. On January 22, 2019, Platinum-Montaur filed its brief in the Second Circuit, asking the Second Circuit to reverse the District Court and remand the case to the District Court for further proceedings. The Second Circuit held oral argument in this matter on September 5, 2019. On November 25, 2019, the Second Circuit issued a decision which remanded the case to the District Court for further consideration of whether the District Court had jurisdiction over the case following removal from the New York Supreme Court. The Second Circuit did not address the merits of Platinum-Montaur's allegations against Navidea. By agreement of the parties, the case 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. In addition, the New York Supreme Court stopped accepting non-emergency filings due to the pandemic emergency. At present, it is unknown how long the disruptions due to the pandemic emergency will last, and thus uncertain as to the timeline under which the matter will progress in the New York Supreme Court. 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 will be held in escrow for up to 18 months in order to reimburse Navidea in the event that Navidea is obligated to pay any portion of the Platinum debt to a party other than Dr. Goldberg. Further, the Goldberg Agreement provided that the Company's subsidiary, MT, would redeem all of Dr. Goldberg's preferred stock and issue to Dr. Goldberg super voting common stock equal to 5% of the outstanding shares of MT. In November 2018, the Company issued 925,000 shares of our Common Stock to Dr. Goldberg, 250,000 of which were placed in escrow in accordance with the Goldberg Agreement.

On February 11, 2019, Dr. Goldberg represented to the MT Board that he had, without MT Board or shareholder approval, created a subsidiary of MT, transferred all of the assets of MT into the subsidiary, and then issued himself stock in the subsidiary. On February 19, 2019, Navidea notified MT that it was terminating the sublicense in accordance with its terms, effective March 1, 2019, due to MT's insolvency. On February 20, 2019, the MT Board removed Dr. Goldberg as President and Chief Executive Officer of MT and from any other office of MT to which he may have been appointed or in which he was serving. Dr. Goldberg remains a member of the MT Board, together with Michael Rice and Dr. Claudine Bruck. Mr. Rice and Dr. Bruck remain members of the board of directors of Navidea. The MT Board then appointed Jed A. Latkin to serve as President and Chief Executive Officer of MT.

New York Litigation Involving Dr. Goldberg

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

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

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

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

On January 31, 2020, Dr. 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. The discovery deadline in the New York Action is June 15, 2020.

Delaware Litigation Involving Dr. Goldberg

On February 20, 2019, MT initiated a suit against Dr. Goldberg in the Court of Chancery of the State of Delaware, alleging, among other things, breach of fiduciary duty as a director and officer of MT and conversion, and to obtain a declaratory judgment that the transactions Dr. Goldberg caused MT to effect are void. On June 12, 2019, the Delaware Court found that Dr. Goldberg's actions were not authorized in compliance with the Delaware General Corporate Law. Specifically, the Delaware Court found that Dr. Goldberg's creation of a new subsidiary of MT and the purported assignment by Dr. Goldberg of MT's intellectual property to that subsidiary were void. The Delaware Court's ruling follows the order on May 23, 2019 in the case, in which it found Dr. Goldberg in contempt of its prior order holding Dr. Goldberg responsible for the payment of MT's fees and costs to cure the damages caused by Dr. Goldberg's contempt. MT's claims for breach of fiduciary duty and conversion against Dr. Goldberg remain pending. As a result of the Delaware Court's ruling and Navidea's prior termination of the sublicense between itself and MT, all of the intellectual property related to the Manocept platform is now directly controlled by Navidea. A trial on MT's claims against Goldberg for breach of fiduciary duty and conversion is presently scheduled for June 2020. However, due to COVID-19 impacts on the judicial system, the Company expects that the trial date will be adjourned to a future date.

Derivative Action Involving Dr. Goldberg

On July 26, 2019, Dr. Goldberg served shareholder demands on the Boards of Navidea and MT repeating many of the claims made in the lawsuits described above. On or about November 20, 2019, Dr. Goldberg commenced a derivative action purportedly on behalf of MT in the District Court against Dr. Claudine Bruck, Y. Michael Rice, and Jed Latkin alleging a claim for breach of fiduciary duty based on the actions alleged in the demands. On April 3, 2020, Dr. Goldberg dismissed the derivative action in New York without prejudice and retains the ability to re-file the action in Delaware. See Notes 2 and 6.

NYSE American Continued Listing Standards

On August 14, 2018, the Company received a Deficiency Letter from the NYSE American stating that Navidea was not in compliance with certain NYSE American continued listing standards relating to stockholders' equity. Specifically, Navidea was not in compliance with Sections 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide (the "Guide"), the highest of such standards requiring an issuer to have stockholders' equity of $6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years. In addition, the Deficiency Letter stated that the NYSE American staff (the "Staff") determined that the Company's securities had been selling for a low price per share for a substantial period of time and, pursuant to Section 1003(f)(v) of the Guide, Navidea's continued listing was predicated on it effecting a reverse stock split of our Common Stock or otherwise demonstrating sustained price improvement within a reasonable period of time.

The Company regained compliance with the minimum trading price standard following a one-for-twenty reverse split of its issued and outstanding Common Stock on April 26, 2019.

On February 14, 2020, the Company announced the execution of several funding transactions resulting in stockholders' equity of $6.0 million, which brought the Company back into compliance with Sections 1003(a)(i), (ii) and (iii) of the Guide within the timeframe permitted by the NYSE American. However, much of the funding from these transactions has been delayed, due in part to the COVID-19 pandemic and its devastating impact on global financial markets. The Company is working closely with the parties to these transactions to complete the funding as soon as possible. The Company had a stockholders' deficit of approximately $1.8 million as of March 31, 2020.

11. 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, resulting in approximately $812,000 of stock subscriptions receivable as of December 31, 2019. The remaining $812,000 of proceeds were received and the related Common Stock was issued in January 2020. In accordance with current accounting guidance, the $812,000 of stock subscriptions receivable was included in accounts and other receivables in the consolidated balance sheet at 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. Of this amount, approximately $850,000 was received during the first quarter of 2020. An additional $1.7 million was received and the related Common Stock was issued during the second quarter of 2020 through the date of filing this Quarterly Report on Form 10-Q. As a result, the Company recorded approximately $1.7 million of stock subscriptions receivable as of March 31, 2020. The remaining $913,000 of proceeds have not been received as of the date of filing this Quarterly Report on Form 10-Q. In accordance with current accounting guidance, the $1.7 million of stock subscriptions receivable was included in accounts and other receivables, and the $913,000 of stock subscriptions receivable was included in common stock subscriptions receivable in the consolidated balance sheet at March 31, 2020.

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

During the three-month period ended March 31, 2020, we issued 53,315 shares of our common stock valued at $65,000 to our employees as partial payment in lieu of cash for their 2019 bonuses.

12. Stock Warrants

At March 31, 2020, there are 1.4 million 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 $13.26 per share. The warrants have remaining outstanding terms ranging from one to 15.4 years.

13. Income Taxes

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

Current accounting standards require a valuation allowance against DTAs if, based on the weight of available evidence, it is more likely than not that some or all of the DTAs may not be realized. Due to the uncertainty surrounding the realization of these DTAs in future tax returns, all of the DTAs have been fully offset by a valuation allowance at March 31, 2020 and December 31, 2019, except the alternative minimum tax ("AMT") credit carryforward amount described below.

In assessing the realizability of DTAs, management considers whether it is more likely than not that some portion or all of the DTAs will not be realized. The ultimate realization of DTAs is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods) and projected future taxable income in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the DTAs are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences or tax carryforwards as of March 31, 2020, except for the AMT credit carryforward.

The Tax Cuts and Jobs Act (the "Tax Act") was signed into law on December 22, 2017. The Tax Act repealed the AMT for corporations, and permits any existing AMT credit carryforwards to be used to reduce the regular tax obligation in 2018, 2019 and 2020. Under the Tax Act, companies may continue using AMT credits to offset any regular income tax liability in years 2018 through 2020, with 50% of remaining AMT credits refunded in each of the 2018, 2019 and 2020 tax years, and all remaining credits refunded in tax year 2021. This results in full realization of an existing AMT credit carryforward irrespective of future taxable income. Accordingly, the Company recorded AMT credit carryforwards of $621,000 as of December 31, 2019, 50% of which was included in prepaid expenses and other current assets, and 50% of which was included in other noncurrent assets as of December 31, 2019.

The CARES Act was signed into law on March 27, 2020. Under the CARES Act, corporate AMT credits are now 100% refundable as early as the 2018 tax year. Accordingly, the Company has filed for the refund of all $621,000 of AMT credit carryforwards, and they are included in prepaid expenses and other current assets as of March 31, 2020.

Current accounting standards include guidance on the accounting for uncertainty in income taxes recognized in the financial statements. Such standards also prescribe a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company believes that the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of March 31, 2020 or December 31, 2019 and we do not expect any significant changes in the next twelve months. Should we need to accrue interest or penalties on uncertain tax positions, we would recognize the interest as interest expense and the penalties as a selling, general and administrative expense. As of March 31, 2020, tax years 2016-2019 remained subject to examination by federal and state tax authorities.

As of March 31, 2020, we had approximately $142.2 million of federal and $20.1 million of state net operating loss carryforwards, as well as approximately $8.8 million of federal R&D credit carryforwards.

14. Segments

We report information about our operating segments using the "management approach" in accordance with current accounting standards. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. We manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform, and NAV4694 (sublicensed in April 2018), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform.

Certain prior period amounts also have been reclassified to conform to the current period presentation. An adjustment has been made to the Consolidated Statements of Operations for the three-month period ended March 31, 2019, to classify sublease revenue of $94,000 as a reduction in Selling, General and Administrative Expense. This change in classification does not affect previously reported net loss on the Consolidated Statement of Operations.

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

Three Months Ended March 31, 2020	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 15,221	$ —	$ —	$ 15,221
Grant and other revenue	58,916	82,135	—	141,051
Total revenue	74,137	82,135	—	156,272
Cost of revenue	609	—	—	609
Research and development expenses	957,626	41,643	—	999,269
Selling, general and administrative expenses, excluding depreciation and amortization [1]	—	(1,522)	1,812,433	1,810,911
Depreciation and amortization [2]	—	—	16,843	16,843
(Loss) income from operations [3]	(884,098)	42,014	(1,829,276)	(2,671,360)
Other expense [4]	—	—	(2,248)	(2,248)
Net loss	(884,098)	42,014	(1,831,524)	(2,673,608)
Total assets, net of depreciation and amortization:				
United States	$ 36,671	$ 2,494	$ 4,438,066	$ 4,477,231
International	—	—	—	—
Capital expenditures	—	—	6,459	6,459

Three Months Ended March 31, 2019	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 3,150	$ —	$ —	$ 3,150
Grant and other revenue	35,991	2,483	—	38,474
Total revenue	39,141	2,483	—	41,624
Cost of revenue	6,126	—	—	6,126
Research and development expenses	740,583	—	—	740,583
Selling, general and administrative expenses, excluding depreciation and amortization [1]	—	11,714	1,680,023	1,691,737
Depreciation and amortization [2]	—	—	36,779	36,779
Loss from operations [3]	(707,568)	(9,231)	(1,716,802)	(2,433,601)
Other income [4]	—	—	8,713	8,713
Provision for income taxes	(256)	(3)	(617)	(876)
Net loss from continuing operations	(707,824)	(9,234)	(1,708,706)	(2,425,764)
Loss from discontinued operations, net of tax	(3,297)	—	—	(3,297)
Net loss	(711,121)	(9,234)	(1,708,706)	(2,429,061)
Total assets, net of depreciation and amortization:				
United States	$ 55,213	$ 2,411	$ 4,891,112	$ 4,948,736
International	10,422	—	602	11,024
Capital expenditures	—	—	—	—

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

(2) Depreciation and amortization are reflected in selling, general and administrative expenses ($16,843 and $36,779 for the three-month periods ended March 31, 2020 and 2019, respectively).

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

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

15. Supplemental Disclosure for Statements of Cash Flows

During the three-month periods ended March 31, 2020 and 2019, we paid interest aggregating $3,000 and $4,000, respectively. During the three-month period ended March 31, 2020, we issued 53,315 shares of our common stock valued at $65,000 to our employees as partial payment in lieu of cash for their 2019 bonuses.

16. Subsequent Events

The Company has evaluated events and transactions subsequent to March 31, 2020 and through the date these consolidated financial statements were included in this Quarterly Report on Form 10-Q and filed with the SEC.

a. Common Stock: 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. Of this amount, approximately $850,000 was received during the first quarter of 2020. An additional $1.7 million was received and the related Common Stock was issued during the second quarter of 2020 through the date of filing this Quarterly Report on Form 10-Q. As a result, the Company recorded approximately $1.7 million of stock subscriptions receivable as of March 31, 2020. The remaining $913,000 of proceeds have not been received as of the date of filing this Quarterly Report on Form 10-Q.

b. Preferred Stock: In February 2020, the Company executed a binding term sheet to sell the Judgment entered by the Ohio Court of Common Pleas in favor of Navidea in the amount of $4.3 million plus interest, for $4.2 million of proceeds to Navidea. On May 6, 2020, the Company entered into a Stock Purchase Agreement and Letter of Investment Intent with Keystone pursuant to which the Company agreed to issue to Keystone 420,000 shares of newly-designated Series C Preferred Stock for an aggregate purchase price of $4.2 million. Pursuant to the Stock Purchase Agreement, Keystone will purchase shares of Series C Preferred Stock in amounts to be determined by Keystone in one or more closings (each, a "Call Closing") on or before November 6, 2020, provided that all of the Series C Preferred Stock must be purchased by such date.

Holders of the Series C Preferred Stock may convert some or all of the Series C Preferred Stock into shares of the Company's Common Stock at a 10% discount to market (the "Conversion Shares"), provided that the Company may not issue such Conversion Shares in excess of 19.99% of the number of shares of Company common stock outstanding as of the date of the investment (the "Exchange Cap") without shareholder approval, which the Company is not required to seek. In the event that (a) the Company does not have enough Conversion Shares registered for resale so as to allow for a requested conversion and immediate resale, or (b) if the number of Conversion Shares issued reaches the Exchange Cap, then the Company will be required to redeem the difference in cash at $11 per share of Series C Preferred Stock, but only if, when and to the extent that the Company has received cash proceeds as a result of the Judgment being affirmed.

c. License Termination: 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 will no longer have 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"). The Wind-Down Activities include, 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 will also transfer 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.

d. Payroll Protection Program Loan: The CARES Act was enacted on March 27, 2020. Among the provisions contained in the CARES Act is the creation of the PPP that provides for 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. The amount that will be forgiven will be calculated in part with reference to the Company's full-time headcount during the eight-week period following the funding of the PPP loan. On April 30, 2020, the Company was informed by the Lender that the Lender received approval from the SBA to fund the Company's request for a PPP Loan. Per the terms of the PPP Loan, the Company will receive total proceeds of $366,000 from the Lender. In accordance with the loan forgiveness requirements of the CARES Act, the Company intends to use the proceeds from the PPP Loan primarily for payroll costs, rent and utilities, thus the Company anticipates that 100% of the loan will be forgiven. The interest rate on the PPP Loan is a fixed rate of 1% per annum. To the extent that the amounts owed under the PPP Loan, or a portion of them, are not forgiven, the Company will be required to make principal and interest payments in monthly installments beginning six months from the date of the PPP Loan. The PPP Loan matures in two years. The PPP Loan includes events of default. Upon the occurrence of an event of default, the Lender will have the right to exercise remedies against the Company, including the right to require immediate payment of all amounts due under the PPP Note.

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, 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;
- our ability to successfully commercialize our drug candidates;
- our ability to raise capital sufficient to fund our development programs;
- 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.

In March 2017, the Company completed the sale to Cardinal Health 414, LLC ("Cardinal Health 414") of its assets related to the Company's radioactive diagnostic agent Tc99m tilmanocept, marketed under the Lymphoseek® trademark, used for lymphatic mapping, lymph node biopsy, and the diagnosis of metastatic spread to lymph nodes for staging of cancer, in Canada, Mexico and the United States.

Other than Tc99m tilmanocept, which the Company has a license to distribute outside of Canada, Mexico and the United States, none of the Company's drug product candidates have been approved for sale in any market.

Our business is focused on two primary types of drug products: (i) diagnostic substances, including Tc99m tilmanocept and other diagnostic applications of our Manocept platform, and NAV4694 (sublicensed in April 2018), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform. See Note 14 to the accompanying consolidated financial statements for more information about our business segments.

Technology and Product Candidates

Our primary development efforts over the last several years were focused on diagnostic products, including Lymphoseek, which was sold to Cardinal Health 414 in March 2017. Our more recent initiatives have been focused exclusively on diagnostic and therapeutic line extensions based on our Manocept platform.

During the ongoing COVID-19 global pandemic, the Company's primary focus 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. To date, we do not believe there has been any appreciable impact to the Company's clinical development and regulatory timelines resulting from COVID-19. Navidea has enrolled sufficient patients in Arm 3 of the Company's ongoing Phase 2b clinical trial (NAV3-31) and is on schedule to deliver interim data in the timeframe previously communicated. The Company's pivotal Phase 3 trial for rheumatoid arthritis (NAV3-33) also remains on track for a second-half 2020 launch as previously communicated. In addition, analysis of the data from the Company's cardiovascular Phase 2b study remains on schedule. Results provided to Navidea thus far 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 cardiovascular disease applications. Navidea continues to anticipate meeting with the FDA in the coming months to discuss upcoming clinical trial designs.

Manocept Platform - Diagnostics and Therapeutics Background

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

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

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

Manocept Platform – Immuno-Diagnostics Clinical Data

Rheumatoid Arthritis

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

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

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

Cardiovascular Disease ("CV")

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

A nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc99m tilmanocept product dosed subcutaneously is complete (ClinicalTrials.gov NCT02542371). The results of this study were presented at two major international meetings (Conference on Retroviruses and Opportunistic Infections ("CROI") and SNMMI, 2017) and published in early release in the *Journal of Infectious Diseases* in January 2017 (published in the circulated version,*Journal of Infectious Diseases* (2017) 215 (8): 1264-1269), confirming that the Tc99m tilmanocept product can both quantitatively and qualitatively target non-calcified plaque in the aortic arch of Acquired Immunodeficiency Syndrome ("AIDS") patients (supported by NIH/NHLBI Grant 1 R43 HL127846-01).

We have also commenced a second Phase1/2 study in cooperation with Massachusetts General Hospital in subjects with HIV that expands the original study in both the scope of the drug administration as well as the diagnostic assessment of the subjects. This study will enroll up to 24 AIDS subjects and healthy controls in imaging non-calcified plaque using IV and SC-administered Tc99m tilmanocept and will expand the initial investigation to the assessment of aortic plaque as well as carotid and coronary arteries. Initial images from this study are currently being evaluated.

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

Kaposi's Sarcoma

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

Colorectal Cancer ("CRC") and Synchronous Liver Metastases

During 2017, we initiated an imaging study in subjects with CRC and liver metastases via IV administration of Tc99m tilmanocept. This study was supported through a SBIR grant (NIH/NCI 1 R44 CA1962783-01A1; ClinicalTrials.gov NCT03029988). The trial intended to enroll up to 12 subjects with dose modification. After an interim analysis of the first three completed subjects, a decision was made to not continue with the trial and the study is now closed. An initial presentation took place at SNMMI in June of 2018. An additional report has been submitted to the National Cancer Institute ("NCI") on the early results of this study. The final study report has been completed and submitted to the FDA.

Nonalcoholic Steatohepatitis

We have concluded a clinical study (ClinicalTrials.gov NCT03332940) that was originally designed to enroll 12 subjects with IV administration of Tc99m tilmanocept and an imaging comparator to identify and quantify the extent of NASH lesions in human patients. A semiquantitative evaluation of the images from the first six subjects indicated that imaging the remaining six subjects planned in the study may not sufficiently further our knowledge of Tc99m tilmanocept imaging in individuals with NASH to justify continuing the study using the current protocol. The study is now complete. Ongoing quantitative analyses of the images from the first six subjects will determine if future studies in subjects with NASH are likely to be productive. Initial results were presented at the NASH Summit in Boston in April 2018, and the results are available on Navidea's website.

Tuberculosis ("TB")

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

Biomarker Application and Qualification

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

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

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

We have already reported on the peripheral infectious disease aspects of KS, including HIV and HHV8 (CROI, Boston 2016, and KS HHV8 Summit Miami 2015). As noted, we continue this work funded by the NIH/NIAID and NCI. The Company has completed preclinical studies employing both MT 1000-class and 2000-class therapeutic conjugates of Manocept. The positive results from these studies are indicative of Manocept's specific targeting supported by its strong binding affinity to CD206 receptors. This high degree of specificity is a foundation of the potential for this technology to be useful in treating diseases linked to the over-activation of macrophages. This includes various cancers as well as autoimmune, infectious, CV, and central nervous system ("CNS") diseases.

Kaposi's Sarcoma

The novel MT-1000 class constructs are designed to specifically deliver doxorubicin, a chemotoxin, which can kill KS tumor cells and their tumor-associated macrophages, potentially altering the course of cancer. We have received additional funding to continue therapeutic studies in this disease with the goal of completing an investigational new drug ("IND") submission for a Manocept construct (MT-1000 class of compounds) consisting of tilmanocept linked to doxorubicin for the treatment of KS. The first part of the grant, now complete, supported analyses including *in vitro* and cell culture studies, to be followed by Parts 2 and 3 FDA-required preclinical animal testing studies. The information from these studies will be combined with other information in an IND application that will be submitted to the FDA requesting permission to begin testing the compound in selected KS subjects (supported by NIH/NCI 1 R44 CA206788-01).

Other Immunotherapeutic Applications

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

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 $999,000 and $741,000 in total on research and development activities during the three-month periods ended March 31, 2020 and 2019, 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:

	Three Months Ended March 31,	
Development Program [(a)]	**2020**	**2019**
Manocept Platform – Diagnostics	$ 527,254	$ 205,160
Manocept Platform – Therapeutics	42,193	166,988
Tc99m Tilmanocept	(550)	9,750

(a) Certain development program expenditures were offset by grant reimbursement revenues totaling $141,000 and $21,000 during the three-month periods ended March 31, 2020 and 2019, respectively.

We expect to continue the advancement of our efforts with our Manocept platform during the remainder of 2020. We currently expect our total research and development expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be higher in 2020 than in 2019. However, COVID-19 continues to spread globally, which has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities and our supply chain. To date, there has been no appreciable impact to the Company's clinical development and regulatory timelines resulting from COVID-19. However, it is still possible that the COVID-19 outbreak may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver clinical drug supplies on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

The extent to which the 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 of COVID-19 and the actions to contain or treat its impact, among others. 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. To date, much of the funding from the February 2020 transactions described below in "Liquidity and Capital Resources" has been delayed, due in part to the COVID-19 pandemic and its devastating impact on global financial markets. The Company is working closely with the parties to these transactions to complete the funding as soon as possible.

Tc99m tilmanocept is approved by the EMA for use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity in the EU. We anticipate that we will incur costs related to supporting our product, regulatory, manufacturing and commercial activities related to the potential marketing registration and sale of Tc99m tilmanocept in markets other than the EU. There can be no assurance that Tc99m tilmanocept will achieve regulatory approval in any market other than the EU, or if approved in those markets, that it will achieve market acceptance in the EU or any other market.

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

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

Three Months Ended March 31, 2020 and 2019

Royalty Revenue. During the first quarters of 2020 and 2019, we recognized royalty revenue of $15,000 and $3,000, respectively, related to our license agreement with SpePharm AG (an affiliate of Norgine BV) in Europe.

Grant and Other Revenue. During the first quarters of 2020 and 2019, we recognized grant and other revenue of $141,000 and $38,000, respectively. Grant revenue of $141,000 and $21,000 during the first quarters of 2020 and 2019, respectively, was primarily related to SBIR grants from the NIH supporting Manocept development.

Research and Development Expenses. Research and development expenses increased $258,000, or 35%, to $999,000 during the first quarter of 2020 from $741,000 during the same period in 2019. The increase was primarily due to net increases in drug project expenses related to (i) increased Manocept diagnostic development costs of $322,000 including increased clinical trial costs and increased manufacturing-related activities; and (ii) increased NAV4694 development costs of $15,000 resulting from the reversal of certain clinical development cost accruals in the first quarter of 2019; offset by (iii) decreased Manocept therapeutic development costs of $125,000 including decreased preclinical and clinical development costs; and (iv) decreased Tc99m tilmanocept development costs of $10,000 including decreased license fees. The net increase in research and development expenses also included increased compensation including incentive-based awards of $73,000 related to net increased headcount and salaries, offset by decreased general office expenses of $11,000 and decreased regulatory consulting costs of $6,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $99,000, or 6%, to $1.8 million during the first quarter of 2020 from $1.7 million during the same period in 2019. Increased legal and professional services of $119,000, increased compensation including incentive-based awards of $34,000, and increased franchise taxes of $30,000 were offset by decreased depreciation and amortization expenses of $20,000, decreased insurance costs of $19,000, decreased travel expenses of $19,000, and decreased investor relations costs of $13,000.

Other Income (Expense). Other expense, net, was $2,000 during the first quarter of 2020 compared to other income, net of $9,000 during the same period in 2019. During the first quarters of 2020 and 2019, we recognized interest income of $1,000 and $13,000, respectively. During the first quarters of 2020 and 2019, we recognized interest expense of $3,000 and $4,000, respectively.

Liquidity and Capital Resources

Cash balances decreased to $601,000 at March 31, 2020 from $1.0 million at December 31, 2019. The net decrease was primarily due to cash used to fund our operations of $951,000, payments on notes payable of $130,000 and patent and trademark costs of $58,000, offset by net proceeds from issuance of common stock of $700,000.

Operating Activities. Cash used in operations was $951,000 during the first quarter of 2020 compared to $2.2 million used during the same period in 2019.

Accounts and other receivables increased to $1.7 million at March 31, 2020 from $901,000 at December 31, 2019, primarily due to the increased common stock subscriptions of $843,000 offset by the receipt of grant reimbursements of $46,000.

Prepaid expenses and other current assets increased to $1.1 million at March 31, 2020 from $967,000 at December 31, 2019, primarily due to the acceleration of expected AMT tax credit refund timing to the current year, offset by normal amortization of prepaid insurance.

Accounts payable increased to $1.5 million at March 31, 2020 from $1.1 million at December 31, 2019, primarily driven by net increased payables due for legal and professional services, offset by decreased payables due to clinical development activities. Accrued liabilities and other current liabilities increased to $2.4 million at March 31, 2020 from $2.1 million at December 31, 2019, primarily related to increased accruals for legal and professional services and Manocept development costs. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our development activity related to the Manocept platform.

Investing Activities. Investing activities used $64,000 during the first quarter of 2020 compared to $227,000 provided during the same period in 2019. Patent and trademark costs used $58,000 and purchases of property and equipment used $6,000 during the first quarter of 2020. Maturities of available-for-sale securities provided $200,000 and the return of previously-purchased property and equipment provided $27,000 during the first quarter of 2019.

Financing Activities. Financing activities provided $570,000 during the first quarter of 2020 compared to $67,000 used during the same period in 2019. The $570,000 provided by financing activities in the first quarter of 2020 consisted primarily of proceeds from issuance of common stock of $850,000, offset by payment of common stock issuance costs of $150,000 and principal payments on financed insurance premiums of $130,000. The $67,000 used by financing activities in the first quarter of 2019 consisted primarily of principal payments on financed insurance premiums of $117,000, offset by proceeds from issuance of common stock of $50,000.

Registered Offerings

On February 14, 2020, we executed an agreement with an investor to purchase 1,647,059 million shares of our Common Stock at a price of $0.85 per share for aggregate gross proceeds to Navidea of approximately $1.4 million. The offering was made pursuant to our shelf registration statement on Form S-3 (Registration No. 333-222092), which was declared effective by the Securities and Exchange Commission (the "SEC") on December 27, 2017, including the prospectus contained therein, as well as a prospectus supplement filed with the SEC on February 18, 2020. We intend to use the net proceeds from this offering to fund our research and development programs, including continued advancement of our two Phase 2b and Phase 3 clinical trials of Tc99m tilmanocept in patients with rheumatoid arthritis, and for general working capital purposes and other operating expenses. See Notes 2, 11 and 16(a) to the accompanying consolidated financial statements.

Private Placements

On February 13, 2020, we executed a stock purchase agreement with John K. Scott, Jr. to purchase approximately 2.4 million shares of Common Stock for aggregate gross proceeds of approximately $2.0 million. We intend to use the net proceeds from this private placement to fund our research and development programs, including continued advancement of our two Phase 2b and Phase 3 clinical trials of Tc99m tilmanocept in patients with rheumatoid arthritis, and for general working capital purposes and other operating expenses. The securities offered and sold in the private placement to Mr. Scott were not registered under the Securities Act of 1933, as amended, or state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from registration requirements. We have agreed to file a registration statement with the SEC covering the resale of the shares of Common Stock issued to Mr. Scott. See Notes 2, 11 and 16(a) to the accompanying consolidated financial statements.

CRG Litigation

On February 13, 2020, the Company executed a binding term sheet to sell the Judgment for $4.2 million of proceeds to Navidea. On May 6, 2020, the Company entered into a Stock Purchase Agreement and Letter of Investment Intent with Keystone pursuant to which the Company agreed to issue to Keystone 420,000 shares of newly-designated Series C Preferred Stock for an aggregate purchase price of $4.2 million. The Series C Preferred Stock will be guaranteed by a portion of the proceeds of the Judgment. See Notes 2 and 16(b) to the accompanying consolidated financial statements.

Platinum Litigation

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

Goldberg Agreement and Litigation

See Notes 2, 6 and 10 to the accompanying consolidated financial statements.

Paycheck Protection Program Loan

The CARES Act was enacted on March 27, 2020. Among the provisions contained in the CARES Act is the creation of the PPP that provides for 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. The amount that will be forgiven will be calculated in part with reference to the Company's full-time headcount during the eight-week period following the funding of the PPP loan. On April 30, 2020, the Company was informed by the Lender that the Lender received approval from the SBA to fund the Company's request for a PPP Loan. Per the terms of the PPP Loan, the Company will receive total proceeds of $366,000 from the Lender. In accordance with the loan forgiveness requirements of the CARES Act, the Company intends to use the proceeds from the PPP Loan primarily for payroll costs, rent and utilities, thus the Company anticipates that 100% of the loan will be forgiven. See Notes 2 and 16(d) to the accompanying consolidated financial statements.

Summary

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

We plan to focus our resources during 2020 primarily on development of products based on the Manocept platform. Although management believes that it will be able to achieve this objective, it is subject to a number of variables beyond our control, including the nature and timing of any partnering opportunities, the ability to modify contractual commitments made in connection with these programs, and the timing and expense associated with suspension or alteration of clinical trials, and consequently we may need to seek additional financing in order to support our planned development programs.

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

The Company is currently engaged in litigation with Dr. Goldberg, CRG and Platinum-Montaur. In addition, the Company has experienced recurring net losses and has used significant cash to fund its operations. The Company has considerable discretion over the extent of development project expenditures and has the ability to curtail the related cash flows as needed. The Company also has funds remaining under outstanding grant awards, and continues working to establish new sources of funding, including collaborations, potential equity investments, and additional grant funding that can augment the balance sheet. However, COVID-19 continues to spread globally, which has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities and our supply chain. To date, we do not believe there has been any appreciable impact to the Company's clinical development and regulatory timelines resulting from COVID-19. 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. To date, much of the funding from the February 2020 transactions described above has been delayed, due in part to the COVID-19 pandemic and its devastating impact on global financial markets. The Company is working closely with the parties to these transactions to complete the funding as soon as possible. Based on our current working capital and our projected cash burn, and without definitive agreements in place for additional funding, management believes that there is substantial doubt about the Company's ability to continue as a going concern for at least twelve months following the issuance of this Quarterly Report on Form 10-Q. See Note 2 to the accompanying consolidated financial statements.

In addition, 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. The Company will continue to evaluate the impact that these events could have on the operations, financial position, and the results of operations and cash flows during fiscal year 2020 and beyond.

Off-Balance Sheet Arrangements

As of March 31, 2020, we had no off-balance sheet arrangements.

Recent Accounting Standards

See Notes 1(e) and 1(f) to the accompanying 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 primarily from grants to support various product development initiatives. We generally recognize grant revenue when expenses reimbursable under the grants have been paid and payments under the grants become contractually due.

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

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

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

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

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

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

- *Fair Value of Warrants.* We estimate the fair value of warrants using the Black-Scholes model, which is affected by our stock price and warrant exercise price, as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility and risk-free interest rate.

Item 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 March 31, 2020, 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 March 31, 2020, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

See Note 10 to the accompanying consolidated financial statements.

Item 1A. Risk Factors

There have been no material changes to the Company's risk factors as previously reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 18, 2020, except as described below.

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

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our development and commercialization efforts may be adversely affected. The COVID-19 pandemic continues to spread globally, which has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities and our supply chain. During the ongoing COVID-19 global pandemic, the Company's primary focus 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.

To date, we do not believe there has been any appreciable impact to the Company's clinical development and regulatory timelines resulting from COVID-19. However, it is still possible that the COVID-19 outbreak may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver clinical drug supplies on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

The extent to which the 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 of COVID-19 and the actions to contain or treat its impact, among others. 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.

In connection with the COVID-19 pandemic, the following risks could have a material effect on our business, financial condition, results of operations and prospects:

- The inability or unwillingness of some patients to visit hospitals or clinics in order to enroll in clinical trials;
- The inability of global suppliers of raw materials or components used in the manufacture of our products, or contract manufacturers of our products, to supply and/or transport those raw materials, components and products to us in a timely and cost effective manner due to shutdowns, interruptions or delays, limiting and precluding the production of our finished products, impacting our ability to supply customers, reducing our sales, increasing our costs of goods sold, and reducing our absorption of overhead;
- The reduced capacity or productivity of as a result of possible illness, quarantine or other inability of our employees and contractors to work, despite all of the preventative measures we continue to undertake to protect the health and safety of our workforce;
- The illiquidity or insolvency of our suppliers, vendors and customers, or their inability to pay our invoices in full or in a timely manner, due to the reduction in their revenues caused by the cancellation or delay of procedures and other factors, which could potentially reduce our cash flow and our liquidity;
- Delays in our ability, and the ability of our development partners, to conduct, enroll and complete clinical development programs such as the Company's Phase 2b clinical trial (NAV3-31) and Phase 3 clinical trial for rheumatoid arthritis (NAV3-33);
- Delays of regulatory reviews and approvals, including with respect to our product candidates, by the FDA or other health or regulatory authorities;
- Our ability to maintain employee morale and motivate and retain management personnel and other key employees;
- The instability to worldwide economies, financial markets, social institutions, labor markets and the healthcare systems as a result of the COVID-19 pandemic, which could result in an economic downturn that could adversely impact our business, results of operations and financial condition, as well as that of our investors, suppliers, customers or other business partners. For example, to date, much of the funding from the February 2020 transactions described above in "Liquidity and Capital Resources" has been delayed, due in part to the COVID-19 pandemic and its devastating impact on global financial markets. The Company is working closely with the parties to these transactions to complete the funding as soon as possible; and
- A recurrence of the COVID-19 pandemic after social distancing and other similar measures have been relaxed.

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	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.
** Furnished herewith.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
May 15, 2020

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.

May 15, 2020

/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.

May 15, 2020

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