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

FORM 10-Q

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

For the quarterly period ended June 30, 2019

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: 18,059,406 shares of common stock, par value $.001 per share (as of the close of business on August 1, 2019).

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

	June 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,062,857	$ 3,475,881
Available-for-sale securities	200,188	799,270
Accounts and other receivables	206,863	21,151
Prepaid expenses and other	1,004,890	1,299,454
Total current assets	6,474,798	5,595,756
Property and equipment	1,212,090	1,251,185
Less accumulated depreciation and amortization	1,135,466	1,089,013
Property and equipment, net	76,624	162,172
Right-of-use lease assets	397,783	—
Less accumulated amortization	60,901	—
Right-of-use lease assets, net	336,882	—
License agreements, patents and trademarks	480,404	480,404
Less accumulated amortization	66,744	51,912
License agreements, patents and trademarks, net	413,660	428,492
Other assets	828,431	835,107
Total assets	$ 8,130,395	$ 7,021,527
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 673,021	$ 424,718
Accrued liabilities and other	2,323,144	2,517,047
Notes payable	80,024	316,074
Lease liabilities, current	250,946	—
Terminated lease liability, current	—	120,679
Deferred revenue, current	495,000	—
Total current liabilities	3,822,135	3,378,518
Lease liabilities	613,753	—
Terminated lease liability	—	468,494
Deferred revenue	700,000	700,000
Other liabilities	63,000	64,055
Total liabilities	5,198,888	4,611,067
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock; $.001 par value; 300,000,000 shares authorized; 18,059,406 and 10,019,535 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	209,056	200,391
Additional paid-in capital	343,879,087	338,265,383
Accumulated deficit	(341,825,130)	(336,722,905)
Accumulated other comprehensive gain (loss)	188	(730)
Total Navidea stockholders' equity	2,263,201	1,742,139
Noncontrolling interest	668,306	668,321
Total stockholders' equity	2,931,507	2,410,460
Total liabilities and stockholders' equity	$ 8,130,395	$ 7,021,527

See accompanying notes to consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Royalty revenue	$ 5,940	$ 6,665	$ 9,090	$ 7,460
License revenue	9,953	257,709	9,953	257,709
Grant and other revenue	244,199	277,753	282,673	553,403
Total revenue	260,092	542,127	301,716	818,572
Cost of revenue	238	35,392	6,364	35,710
Gross profit	259,854	506,735	295,352	782,862
Operating expenses:				
Research and development	1,070,642	1,142,718	1,811,225	2,141,674
Selling, general and administrative	1,861,600	1,789,399	3,590,116	3,565,771
Total operating expenses	2,932,242	2,932,117	5,401,341	5,707,445
Loss from operations	(2,672,388)	(2,425,382)	(5,105,989)	(4,924,583)
Other (expense) income:				
Interest income (expense), net	1,630	(23,547)	11,478	7,840
Loss on extinguishment of debt	—	—	—	(4,265,434)
Other, net	(3,220)	2,828	(4,356)	(1,886)
Total other (expense) income, net	(1,590)	(20,719)	7,122	(4,259,480)
Loss before income taxes	(2,673,978)	(2,446,101)	(5,098,867)	(9,184,063)
Benefit from (provision for) income taxes	168	10,929	(708)	10,929
Loss from continuing operations	(2,673,810)	(2,435,172)	(5,099,575)	(9,173,134)
Discontinued operations, net of tax effect				
Gain (loss) from discontinued operations	632	(1,938)	(2,665)	(1,938)
Gain on sale	—	43,053	—	43,053
Net loss	(2,673,178)	(2,394,057)	(5,102,240)	(9,132,019)
Less loss attributable to noncontrolling interest	(3)	(16)	(15)	(25)
Net loss attributable to common stockholders	$ (2,673,175)	$ (2,394,041)	$ (5,102,225)	$ (9,131,994)
Loss per common share (basic and diluted):				
Continuing operations	$ (0.24)	$ (0.30)	$ (0.48)	$ (1.13)
Discontinued operations	$ —	$ 0.01	$ —	$ 0.01
Attributable to common stockholders	$ (0.24)	$ (0.29)	$ (0.48)	$ (1.12)
Weighted average shares outstanding	11,096,834	8,135,849	10,560,265	8,124,711

See accompanying notes to consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Net loss	$ (2,673,178)	$ (2,394,057)	$ (5,102,240)	$ (9,132,019)
Unrealized (loss) gain on available-for-sale securities	(40)	508	918	332
Comprehensive loss	$ (2,673,218)	$ (2,393,549)	$ (5,101,322)	$ (9,131,687)

See accompanying notes to consolidated financial statements.

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

For the Six Months Ended June 30, 2019

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Compre-hensive Loss	Non-controlling Interest	Total Stockholders' Equity
	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
Rounding adjustments related to reverse stock split	(1,114)	—	(3,385)	—	—	—	(3,385)
Issued stock to 401(k) plan	8,128	8	19,580	—	—	—	19,588
Shares issued for public offering, net of offering costs of $841,559	8,000,000	8,000	5,158,441	—	—	—	5,166,441
Value of warrants issued in connection with public offering	—	—	261,288	—	—	—	261,288
Stock compensation expense	—	—	66,159	—	—	—	66,159
Comprehensive loss:							
Net loss	—	—	—	(2,673,176)	—	(3)	(2,673,179)
Unrealized loss on available-for-sale securities	—	—	—	—	(40)	—	(40)
Total comprehensive loss	—	—	—	—	—	—	(2,673,219)
Balance, June 30, 2019	18,059,406	$ 209,056	$ 343,879,087	$ (341,825,130)	$ 188	$ 668,306	$ 2,931,507

For the Six Months Ended June 30, 2018

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Compre-hensive Loss	Non-controlling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2018	8,110,332	$ 162,207	$ 331,128,787	$ (319,908,968)	$ (2,396)	$ 668,700	$ 12,048,330
Impact of adoption of ASC Topic 606	—	—	—	(700,000)	—	—	(700,000)
Issued stock in payment of employee bonuses	22,920	458	164,563	—	—	—	165,021
Issued restricted stock	10,000	200	—	—	—	—	200
Issued stock to 401(k) plan	4,734	95	35,885	—	—	—	35,980
Stock compensation expense	—	—	137,964	—	—	—	137,964
Comprehensive loss:							
Net loss	—	—	—	(6,737,953)	—	(9)	(6,737,962)
Unrealized loss on available-for-sale securities	—	—	—	—	(176)	—	(176)
Total comprehensive loss	—	—	—	—	—	—	(6,738,138)
Balance, March 31, 2018	8,147,986	162,960	331,467,199	(327,346,921)	(2,572)	668,691	4,949,357
Issued stock in payment of employee bonuses	33,018	660	151,221				151,881
Stock compensation expense	—	—	79,183	—	—	—	79,183
Comprehensive loss:							
Net loss	—	—	—	(2,394,041)	—	(16)	(2,394,057)
Unrealized gain on available-for-sale securities	—	—	—	—	508	—	508
Total comprehensive loss	—	—	—	—	—	—	(2,393,549)
Balance, June 30, 2018	8,181,004	$ 163,620	$ 331,697,603	$ (329,740,962)	$ (2,064)	$ 668,675	$ 2,786,872

See accompanying notes to consolidated financial statements.

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

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (5,102,240)	$ (9,132,019)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	73,505	75,498
Compounded interest on long term debt	—	84,576
Stock compensation expense	128,137	217,147
Loss on extinguishment of debt	—	4,265,434
Value of stock issued to employees	—	316,902
Value of stock issued to 401(k) plan for employer matching contributions	19,588	35,980
Changes in operating assets and liabilities:		
Accounts and other receivables	(185,712)	12,573,372
Prepaid expenses and other assets	(35,643)	371,538
Accounts payable	248,303	(401,323)
Accrued and other liabilities	91,593	(112,274)
Deferred revenue	483,976	(5,037)
Net cash (used in) provided by operating activities	(4,278,493)	8,289,794
Cash flows from investing activities:		
Proceeds from sales of available-for-sale securities	400,000	200,000
Maturities of available-for-sale securities	200,000	800,000
Proceeds from return (payments for purchases) of equipment	26,875	(3,165)
Net cash provided by investing activities	626,875	996,835
Cash flows from financing activities:		
Proceeds from issuance of common stock	6,046,915	200
Payment of common stock issuance costs	(572,271)	—
Payment of debt-related costs	—	(7,153,000)
Principal payments on notes payable	(236,050)	(237,862)
Net cash provided by (used in) financing activities	5,238,594	(7,390,662)
Net increase in cash and cash equivalents	1,586,976	1,895,967
Cash and cash equivalents, beginning of period	3,475,881	2,795,006
Cash and cash equivalents, end of period	$ 5,062,857	$ 4,690,973

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 June 30, 2019 and for the three-month and six-month periods ended June 30, 2019 and 2018 is unaudited, but includes all adjustments (which consist only of normal recurring adjustments) that the management of Navidea Biopharmaceuticals, Inc. ("Navidea", the "Company," or "we") believes to be necessary for the fair presentation of results for the periods presented. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. The balances as of June 30, 2019 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, 2018, 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, and our majority-owned subsidiary, Macrophage Therapeutics, Inc. ("MT"). All significant inter-company accounts were eliminated in consolidation.

On April 26, 2019, the Company effected a one-for-twenty reverse stock split of its issued and outstanding shares of common stock. As a result of the reverse split, each twenty pre-split shares of common stock outstanding automatically combined into one new share of common stock. The number of outstanding common shares was reduced from approximately 201.0 million to approximately 10.1 million shares. The authorized number of shares of common stock was not reduced and remains at 300.0 million. The par value of the Company's common stock remains unchanged at $0.001 per share after the reverse split. Our consolidated balance sheets, statements of operations, statements of stockholders' equity, and accompanying notes to the financial statements have been restated, as required, for all periods presented to reflect the reverse stock split as if it had occurred on January 1, 2018. Our consolidated statements of cash flows were not impacted by the reverse stock split.

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

(2) *Notes payable:* The carrying value of our debt at June 30, 2019 and December 31, 2018 primarily consisted of the face amount of the notes plus accrued interest. At June 30, 2019, the fair value of our notes payable was approximately $80,000, equal to the carrying value of $80,000. At December 31, 2018, the fair value of our notes payable was approximately $316,000, equal to the carrying value of $316,000. See Note 9.

(3) *Derivative liabilities:* Derivative liabilities are related to certain outstanding warrants which are recorded at fair value. Derivative liabilities totaling $63,000 as of June 30, 2019 and December 31, 2018 were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of June 30, 2019 and December 31, 2018 included volatility, a risk-free rate and expected dividends. In addition, we considered non-performance risk and determined that such risk is minimal. Unrealized gains and losses on the derivatives, if any, are classified in other expenses as a change in the fair value of financial instruments in the statements of operations. See Note 4.

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. Recently Adopted Accounting Standards: In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 requires the recognition of right-of-use lease assets and lease liabilities by lessees for those leases classified as operating leases under previous U.S. GAAP. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term.

In July 2018, the FASB issued ASU No. 2018-10,*Codification Improvements to Topic 842, Leases*, and ASU No. 2018-11,*Targeted Improvements to Topic 842, Leases*. ASU 2018-10 updates Topic 842 in order to clarify narrow aspects of the guidance issued in ASU 2016-02*Leases (Topic 842)*. ASU 2018-11 provides entities with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current U.S. GAAP (Topic 840, *Leases*). An entity that elects this transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments in ASU 2018-10 and ASU 2018-11 are effective when ASU 2016-02 is effective, for fiscal years beginning after December 15, 2018.

The Company adopted ASU 2016-02, ASU 2018-10 and ASU 2018-11 effective January 1, 2019 using the cumulative-effect adjustment transition method, which applies the provisions of the standard at the effective date without adjusting the comparative periods presented. Related to the adoption of these standards, the Company made a short-term lease accounting policy election allowing lessees to not recognize right-of-use assets and liabilities for leases with an initial term of 12 months or less.

The adoption of ASU 2016-02 resulted in the recognition of operating lease right-of-use assets and related lease liabilities of approximately $407,000 on the consolidated balance sheet as of January 1, 2019 related to our leases that were previously classified as operating leases, primarily for office space. The adoption of ASU 2016-02 did not materially impact our operating results or liquidity. Disclosures related to the amount, timing and uncertainty of cash flows arising from leases are included in Note 10.

In June 2018, the FASB issued ASU No. 2018-07,*Compensation—Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards, and that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, *Revenue from Contracts with Customers*. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The adoption of ASU 2018-07 did not have a significant impact on our consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-09,*Codification Improvements*. ASU 2018-09 updates a variety of topics in order to clarify, correct errors, or make minor improvements to the Codification, making it easier to understand and easier to apply by eliminating inconsistencies and providing clarifications. Certain amendments in ASU 2018-09 were effective upon issuance, others are effective for annual periods beginning after December 15, 2018 for public business entities, and some have been made to recently issued guidance and will be subject to the effective dates within the relevant guidance. The adoption of ASU 2018-09 did not have a significant 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 is engaged in ongoing litigation with Capital Royalty Partners II L.P. ("CRG") and is currently pursuing recovery of $4.1 million and other damages. See Note 11.

The Company was also 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. ("PPVA"), Platinum Partners Capital Opportunity Fund ("PPCO"), 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. In October 2018, the court granted judgment for Navidea and dismissed all claims in the case, however, in November 2018, Platinum-Montaur filed a notice of appeal. Oral argument has been scheduled before the United States Court of Appeals for the Second Circuit (the "Second Circuit") on September 5, 2019 and the court will issue its decision at some time thereafter. See Notes 9 and 11.

In addition, the Company is engaged in litigation with our former President and Chief Executive Officer, Dr. Michael Goldberg. See Notes 7 and 11.

On June 18, 2019, the Company completed an underwritten public offering of 8,000,000 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock") pursuant to an underwriting agreement (the "Underwriting Agreement"), dated June 13, 2019, between the Company and H.C. Wainwright & Co., LLC (the "Underwriter") at a price to the public of $0.75 per share. Of the 8,000,000 total Shares, 4,000,000 shares were placed with existing investor John K. Scott, Jr. (the "Investor"), at a price of $0.75 per share. Pursuant to the Underwriting Agreement, the Underwriter purchased the remaining 4,000,000 Shares from the Company at a price of $0.69375 per share. After underwriting discounts, commissions, fees and expenses paid to the Underwriter, the Company received net proceeds from the offering of $5,555,000. The Company intends to use the net proceeds from the offering to fund its research and development programs, including continuing to advance its 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 Company is currently engaged in litigation with CRG, Platinum and Dr. Goldberg. 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 recent underwritten public offering provided approximately $5.5 million of additional working capital. 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 Europe, India and China, however Tc99 tilmanocept has only been approved for sale in Europe.

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 10 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 the revenue recognition standard, the upfront payments were recognized upon contract inception, and reimbursement for product development assistance will be recognized on a monthly basis. Should some or all of the variable consideration from milestones, the option and royalties meet the requirements of the revenue recognition standard to be included in the transaction price, those amounts will be recognized as revenue in future periods.

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

During the three-month periods ended June 30, 2019 and 2018, the Company recognized revenue from contracts with customers of approximately $16,000 and $264,000, respectively. During the six-month periods ended June 30, 2019 and 2018, the Company recognized revenue from contracts with customers of approximately $30,000 and $265,000, respectively. During the three-month and six-month periods ended June 30, 2019 and 2018, 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 and six-month periods ended June 30, 2019 and 2018.

Three Months Ended June 30, 2019	**Diagnostics**
Royalty revenue:	
Europe	$ 5,940
License revenue:	
NAV4694 sublicense	$ 9,953

Three Months Ended June 30, 2018	**Diagnostics**
Royalty revenue:	
Europe	$ 6,665
License revenue:	
NAV4694 sublicense	$ 257,709

Six Months Ended June 30, 2019	Diagnostics
Royalty revenue:	
Europe	$ 9,090
License revenue:	
NAV4694 sublicense	$ 9,953
Other revenue:	
Additional stability studies	$ 11,024

Six Months Ended June 30, 2018	Diagnostics
Royalty revenue:	
Europe	$ 7,460
License revenue:	
NAV4694 sublicense	$ 257,709
Other revenue:	
Additional stability studies	$ 15,037

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 are 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 June 30, 2019, 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 and six-month periods ended June 30, 2019 and 2018.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Total deferred revenue, beginning of period	$ 700,000	$ 711,024	$ 711,024	$ 26,061
Impact of adoption of ASU 2014-09 and related standards	—	—	—	700,000
Revenue deferred related to sublicense	495,000	10,000	495,000	10,000
Revenue recognized from satisfaction of performance obligations	—	—	(11,024)	(15,037)
Total deferred revenue, end of period	$ 1,195,000	$ 721,024	$ 1,195,000	$ 721,024

The Company had trade receivables of approximately $0 and $12,000 outstanding as of June 30, 2019 and December 31, 2018.

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

4. Fair Value

The Company's available-for-sale securities consist of certificates of deposit which are measured using Level 2 inputs.

MT issued warrants to purchase MT Common Stock with certain characteristics including a net settlement provision that require the warrants to be accounted for as a derivative liability at fair value on the consolidated balance sheets. The estimated fair value of the MT warrants is $63,000 at both June 30, 2019 and December 31, 2018, is included in other liabilities on the accompanying consolidated balance sheets and will continue to be measured on a recurring basis.

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

Assets and Liabilities Measured at Fair Value on a Recurring Basis as of June 30, 2019

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Certificates of deposit	$ —	$ 200,188	$ —	$ 200,188
Liabilities:				
Liability related to MT warrants	$ —	$ —	$ 63,000	$ 63,000

Assets and Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2018

Description	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Certificates of deposit	$ —	$ 799,270	$ —	$ 799,270
Liabilities:				
Liability related to MT warrants	$ —	$ —	$ 63,000	$ 63,000

a. **Valuation Processes-Level 3 Measurements:** The Company utilizes third-party valuation services that use complex models such as Monte Carlo simulation to estimate the value of our financial liabilities.

b. **Sensitivity Analysis-Level 3 Measurements:** Changes in the valuation of MT as a whole may cause material changes in the fair value of the MT warrants. Significant increases (decreases) in the valuation of MT, such as may be the result of additional financing, could result in a higher (lower) fair value measurement. A change in the valuation of MT would not necessarily result in a directionally similar change in the value of the MT warrants.

There were no Level 1 or Level 2 liabilities outstanding at any time during the six-month periods ended June 30, 2019 and 2018. There were no transfers in or out of our Level 1 or Level 2 liabilities during the six-month periods ended June 30, 2019 or 2018. Changes in the estimated fair value of our Level 3 liabilities relating to unrealized gains (losses), if any, are recorded as changes in fair value of financial instruments in the consolidated statements of operations. There was no change in the estimated fair value of our Level 3 liabilities during the six-month periods ended June 30, 2019 and 2018.

5. Stock-Based Compensation

For the three-month periods ended June 30, 2019 and 2018, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $66,000 and $79,000, respectively. For the six-month periods ended June 30, 2019 and 2018, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately $128,000 and $217,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in any of the three-month or six-month periods ended June 30, 2019 and 2018.

A summary of the status of our stock options as of June 30, 2019, and changes during the six-month period then ended, is presented below.

	Six Months Ended June 30, 2019			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at beginning of period	157,915	$ 24.82		
Granted	95,250	5.89		
Exercised	—	—		
Canceled and Forfeited	(5,304)	8.94		
Expired	(9,041)	31.21		
Outstanding at end of period	238,820	$ 17.38	7.7	$ —
Exercisable at end of period	78,074	$ 33.81	5.1	$ —

A summary of the status of our unvested restricted stock as of June 30, 2019, and changes during the six-month period then ended, is presented below.

	Six Months Ended June 30, 2019	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	5,000	$ 7.42
Granted	15,000	2.75
Vested	(5,000)	7.42
Forfeited	—	—
Unvested at end of period	15,000	$ 2.75

As of June 30, 2019, there was approximately $116,000 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 1.0 year.

6. 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 six-month periods ended June 30, 2019 and 2018 excludes the effects of 1,495,948 and 948,959 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, 15,000 and 7,500 shares of unvested restricted stock for the six-month periods ended June 30, 2019 and 2018, respectively, were excluded in determining basic and diluted loss per share from continuing operations because such inclusion would be anti-dilutive.

7. Investment in Macrophage Therapeutics, Inc.

In August 2018, the Company entered into an Agreement (the "Agreement") with Dr. Michael Goldberg related to his resignation from his positions as an executive officer and a director of Navidea. Among other things, the Agreement provided that Dr. Goldberg would become Chief Executive Officer of MT, and that MT would redeem all of Dr. Goldberg's MT preferred stock and issue to Dr. Goldberg MT super voting common stock equal to 5% of the outstanding shares of MT, subject to execution of one or more additional definitive agreements (the "Definitive Agreements"). As of the date of filing of this Quarterly Report on Form 10-Q, Definitive Agreements have not yet been signed.

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 effective March 1, 2019 because MT became insolvent pursuant to the sublicense agreement. On February 20, 2019, the Board of Directors of MT 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 Mr. Latkin to serve as President and Chief Executive Officer of MT.

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the United States District Court for the Southern District of New York (the "New York Court"), alleging breach of the 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 Agreement is excused and that Navidea is entitled to terminate the 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 Agreement, wrongful termination, injunctive relief, and quantum meruit. Dr. Goldberg also filed a motion to dismiss Navidea's breach of fiduciary duty claim and for an order granting Dr. Goldberg advancement of defense costs, attorneys' fees and sanctions. Navidea has opposed the motion. On July 5, 2019, Navidea and MT moved to dismiss certain of Dr. Goldberg's claims. Dr. Goldberg has opposed the motion. The motions have not been ruled upon.

Also 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, Vice Chancellor Joseph Slights of 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 sub-license between itself and MT, all of the intellectual property related to the Manocept platform is now directly controlled by Navidea.

On July 26, 2019, Dr. Goldberg also served shareholder demands on the Boards of Navidea and MT repeating many of the claims made in the above lawsuits. The respective boards will respond to Dr. Goldberg's demands as appropriate. See Note 11.

8. Accounts Payable, Accrued Liabilities and Other

Accrued liabilities and other at June 30, 2019 and December 31, 2018 includes an aggregate of $309,000 and $1.6 million, respectively, due to related parties for accrued termination costs, bonuses and director fees.

9. Notes Payable

Platinum-Montaur Life Sciences LLC

In July 2012, we entered into an agreement with Platinum-Montaur to provide us with a credit facility of up to $50 million (the "Platinum Loan Agreement"). In March 2017, the Company repaid to PPCO an aggregate of approximately $7.7 million in partial satisfaction of the Company's liabilities, obligations and indebtedness under the Platinum Loan Agreement between the Company and Platinum-Montaur, which were transferred by Platinum-Montaur to PPCO. In November 2018, the Company issued 925,000 shares of common stock of Navidea to Dr. Goldberg, of which approximately 817,857 shares valued at $3.2 million were applied as payment of the Platinum debt, including principal and accrued interest of $2.2 million and loss on extinguishment of debt of $1.0 million. See Note 11.

During the six-month period ended June 30, 2018, $85,000 of interest was compounded and added to the balance of the Platinum Note.

IPFS Corporation

In November 2017, we prepaid $396,000 of insurance premiums through the issuance of a note payable to IPFS Corporation ("IPFS") with an interest rate of 4.0%. The note was payable in ten monthly installments of $40,000, with the final payment made in August 2018. In November 2018, we prepaid $393,000 of insurance premiums through the issuance of a note payable to IPFS with an interest rate of 5.1%. The note is payable in ten monthly installments of $40,000, with the final payment due in August 2019.

Interest expense related to the IPFS notes payable totaled $6,000 and $4,000 during the six-month periods ended June 30, 2019 and 2018, respectively. The balance of the IPFS note was approximately $80,000 and $316,000 as of June 30, 2019 and December 31, 2018, respectively, and was included in notes payable, current in the consolidated balance sheets.

Summary

During the three-month periods ended June 30, 2019 and 2018, we recorded interest expense of $2,000 and $45,000, respectively, related to our notes payable. Of these amounts, $0 and $43,000 was compounded and added to the balance of our notes payable during the three-month periods ended June 30, 2019 and 2018, respectively. During the six-month periods ended June 30, 2019 and 2018, we recorded interest expense of $6,000 and $89,000, respectively, related to our notes payable. Of these amounts, $0 and $85,000 was compounded and added to the balance of our notes payable during the six-month periods ended June 30, 2019 and 2018, respectively.

10. Leases

We currently lease approximately 5,000 square feet of office space at 4995 Bradenton Avenue, Dublin, Ohio, as our principal offices. The current least term expires in June 2020 and provides for a monthly base rent of approximately $3,000. 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. The current lease term expires in October 2022, at a monthly base rent of approximately $26,000 during 2019. 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. The lease term expires in September 2021, at a monthly payment of approximately $300.

We adopted ASU 2016-02, *Leases (Topic 842)* effective January 1, 2019. The following table summarizes the impact of the adoption of ASU 2016-02 on our balance sheet.

	Operating Lease Right-of-Use Assets	Operating Lease Liabilities	Terminated Lease Liability	Deferred Rent
Pre-adoption balance	$ —	$ —	$ 589,173	$ 2,587
Change	406,842	998,602	(589,173)	(2,587)
Post-adoption balance	$ 406,842	$ 998,602	$ —	$ —

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. 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. Total operating lease expense was $55,000 and $121,000 for the three-month and six-month periods ended June 30, 2019, respectively. Sublease income was $94,000 and $189,000 for the three-month and six-month periods ended June 30, 2019, 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 June 30, 2019.

Maturity of Lease Liabilities	Operating Lease Payments
2019 (remaining)	$ 153,858
2020	319,034
2021	306,781
2022	253,339
Total undiscounted operating lease payments	1,033,012
Less imputed interest	168,313
Present value of operating lease liabilities	$ 864,699
Balance Sheet Classification	
Current lease liabilities	$ 250,946
Noncurrent lease liabilities	613,753
Total operating lease liabilities	$ 864,699
Other Information	
Weighted-average remaining lease term for operating leases (in years)	3.2
Weighted-average discount rate for operating leases	12.3%

An initial right-of-use lease asset of $407,000 was recognized as a non-cash asset addition with the adoption of ASU 2016-02. Cash paid for amounts included in the present value of operating lease liabilities was $185,000 during the six-month period ended June 30, 2019 and is included in operating cash flows.

11. Commitments and Contingencies

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

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. The Company is currently considering whether to file a petition for review with the Texas Supreme Court challenging this ruling.

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

The Company has also been engaged in ongoing litigation with CRG in the Court of Common Pleas of Franklin County, Ohio (the "Ohio Court") related to Navidea's claims that the 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 currently pending 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 have resumed in front of the Ohio Court. Following an unsuccessful mediation on May 7, 2019, Navidea moved for Summary Judgment on June 28, 2019. It is anticipated that the Ohio Court will take the Summary Judgment matter under advisement shortly with a written decision to be issued in the future.

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, 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 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. On February 26, 2019, the Company filed its brief in the Second Circuit. Oral argument has been scheduled before the Second Circuit on September 5, 2019 and the court will issue its decision at some time thereafter. See Note 9.

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 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 Agreement provided that Dr. Goldberg would be entitled to 1,175,000 shares of common stock of Navidea, representing in part payment of accrued bonuses and payment of the balance of the Platinum Note. 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 Note to a party other than Dr. Goldberg. Further, the 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 common stock of Navidea to Dr. Goldberg, 250,000 of which were placed in escrow in accordance with the Agreement. As of the date of filing this Quarterly Report on Form 10-Q, Definitive Agreements have not been signed.

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 effective March 1, 2019 because MT became insolvent pursuant to the sublicense agreement. On February 20, 2019, the Board of Directors of MT 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 Mr. Latkin to serve as President and Chief Executive Officer of MT.

On February 20, 2019, Navidea filed a complaint against Dr. Goldberg in the New York Court, alleging breach of the 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 Agreement is excused and that Navidea is entitled to terminate the 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 Agreement, wrongful termination, injunctive relief, and quantum meruit. Dr. Goldberg also filed a motion to dismiss Navidea's breach of fiduciary duty claim and for an order granting Dr. Goldberg advancement of defense costs, attorneys' fees and sanctions. Navidea has opposed the motion. On July 5, 2019, Navidea and MT moved to dismiss certain of Dr. Goldberg's claims. Dr. Goldberg has opposed the motion. The motions have not been ruled upon.

Also on February 20, 2019, MT initiated a suit against Dr. Goldberg in 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, Vice Chancellor Joseph Slights of 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 sub-license between itself and MT, all of the intellectual property related to the Manocept platform is now directly controlled by Navidea.

On July 26, 2019, Dr. Goldberg also served shareholder demands on the Boards of Navidea and MT repeating many of the claims made in the above lawsuits. The respective boards will respond to Dr. Goldberg's demands as appropriate. See Note 7.

NYSE American Continued Listing Standards

On August 14, 2018, the Company received a notification (the "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, the Deficiency Letter stated that Navidea is not in compliance with Section 1003(a)(ii) of the NYSE American Company Guide, which requires an issuer to have stockholders' equity of $4.0 million or more if it has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years. The Deficiency Letter noted that Navidea had stockholders' equity of $2.1 million as of June 30, 2018, and had reported net losses in four of its five most recent fiscal years ended December 31, 2017.

In addition, the Deficiency Letter stated that the Staff determined that the Company's securities have been selling for a low price per share for a substantial period of time and, pursuant to Section 1003(f)(v) of the NYSE American Company Guide, Navidea's continued listing was predicated on it effecting a reverse stock split of its common stock, par value $0.001 per share ("Common Stock") or otherwise demonstrating sustained price improvement within a reasonable period of time.

Navidea was required to submit a plan to the NYSE American by September 14, 2018 advising of actions it has taken or will take to regain compliance with the continued listing standards by February 14, 2020. Navidea submitted a plan by the deadline.

On October 25, 2018, the Company received a notification (the "Acceptance Letter") from the NYSE American that the Company's plan to regain compliance was accepted. The Acceptance Letter also stated that the NYSE American had inadvertently omitted an additional deficiency from the Deficiency Letter. Specifically, the Deficiency Letter should have stated that Navidea is not in compliance with Section 1003(a)(iii) of the NYSE American Company Guide, which requires 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. The Acceptance Letter noted that Navidea had stockholders' equity of $2.1 million as of June 30, 2018, and had reported losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2017.

The Company is required to provide quarterly updates to the NYSE American staff (the "Staff") concurrent with its interim/annual SEC filings. If Navidea fails to regain compliance with the stockholders' equity standards by February 14, 2020, the NYSE American would commence delisting procedures.

On April 2, 2019, the Company received a notification (the "NYSE Letter") from the NYSE American stating that Navidea was not in compliance with Section 1003(a)(i) of the NYSE American Company Guide, which requires an issuer to have stockholders' equity of $2.0 million or more if it has reported losses from continuing operations and/or net losses in two of its three most recent fiscal years. The NYSE Letter noted that Navidea's most recent Form 10-K reported stockholders' equity of $1.7 million as of December 31, 2018, and that Navidea has reported losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2018.

The NYSE Letter also required the Company to regain compliance with the price standard in order to be considered for continued trading through its equity plan period end date of February 14, 2020, subject to periodic review of progress consistent with the equity plan. Accordingly, the Company effected a one-for-twenty reverse split of its issued and outstanding common stock on April 26, 2019.

On April 30, 2019, the Company received a notification (the "Price Compliance Letter") from the NYSE American that the reverse stock split successfully brought the Company back in compliance with the continued listing standards with respect to low selling price as described in Section 1003(f)(v). The Price Compliance Letter also noted that the Company continues to be below compliance with Sections 1003(a)(i), 1003(a)(ii) and 1003(a)(iii), and that if the Company fails to regain compliance with the stockholders' equity standards by February 14, 2020, the NYSE American will commence delisting procedures.

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.

12. Equity

On March 22, 2019, the Company entered into a Stock Purchase Agreement with the Investor, pursuant to which the Company was to issue to the Investor in a private placement (the "Private Placement") up to $3.0 million in shares (the "Securities") of the Company's Common Stock. The Private Placement was to occur in multiple tranches. The initial closing occurred on March 22, 2019 (the "Initial Closing"), at which the Investor purchased $50,000 worth of the Securities at a per share price of $2.80, which was the closing price of a share of Common Stock reported on the NYSE American market for the business day immediately before the Initial Closing Date. The remainder of the Securities were to be purchased by the Investor from time to time, on such date or dates to be determined by the Company and the Investor, which date was not to be later than June 15, 2019. No additional shares were purchased by the Investor prior to the June 15, 2019 expiration of the Stock Purchase Agreement.

On June 18, 2019, the Company completed an underwritten public offering of 8,000,000 Shares of the Company's Common Stock pursuant to the Underwriting Agreement at a price to the public of $0.75 per share. Of the 8,000,000 total Shares, 4,000,000 shares were placed with the Investor at a price of $0.75 per share. Pursuant to the Underwriting Agreement, the Underwriter purchased the remaining 4,000,000 Shares from the Company at a price of $0.69375 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriter an option (the "Underwriter Option"), exercisable for 30 days, to purchase up to an additional 1,200,000 shares of Common Stock at a price per share of $0.69375. The Underwriter Option was not exercised.

The Company paid the Underwriter (a) a management fee equal to 1.0% of the gross proceeds raised in the offering, (b) $50,000 for non-accountable expenses, (c) $100,000 for fees and expenses of legal counsel to the Underwriter and other out-of-pocket expenses, and (d) $10,000 for clearing expenses. After underwriting discounts, commissions, fees and expenses paid to the Underwriter, the Company received net proceeds from the offering of $5,555,000. The Company intends to use the net proceeds from the offering to fund its research and development programs, including continuing to advance its 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.

During the six-month period ended June 30, 2018, we issued 55,938 shares of our common stock valued at $317,000 to our employees as payment in lieu of cash for their 2017 bonuses.

During the six-month periods ended June 30, 2019 and 2018, we issued 8,128 and 4,734 shares of our common stock as matching contributions to our 401(k) Plan which were valued at $20,000 and $36,000, respectively.

13. Stock Warrants

Pursuant to the Underwriting Agreement related to the June 18, 2019 public offering, the Company issued to the Underwriter warrants to purchase 600,000 shares of Common Stock, representing 7.5% of the aggregate number of shares of Common Stock sold in the offering (the "Underwriter Warrants"). The Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending five years from the date of the execution of the Underwriting Agreement, at a price per share equal to $0.9375 (125% of the offering price to the public per Share). The Underwriter Warrants had an estimated fair value of $261,000 at the date of issuance, which was recorded in additional paid-in capital as a reduction of the gross proceeds raised in the public offering. The assumptions used to calculate fair value of the Underwriter Warrants included volatility of 88.6%, a risk-free rate of 1.8% and expected dividends of $0.

At June 30, 2019, there are 1.4 million warrants outstanding to purchase Navidea's common stock. The warrants are exercisable at prices ranging from $0.20 to $50.00 per share with a weighted average exercise price of $13.65 per share. The warrants have remaining outstanding terms ranging from two months to 16.2 years.

In addition, at June 30, 2019, there are 300 warrants outstanding to purchase MT Common Stock. The warrants are exercisable at $2,000 per share.

14. Income Taxes

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

Current accounting standards require a valuation allowance against DTAs if, based on the weight of available evidence, it is more likely than not that some or all of the DTAs may not be realized. Due to the uncertainty surrounding the realization of these DTAs in future tax returns, all of the DTAs have been fully offset by a valuation allowance at June 30, 2019 and December 31, 2018, except the alternative minimum tax ("AMT") credit carryforward amount described below.

In assessing the realizability of DTAs, management considers whether it is more likely than not that some portion or all of the DTAs will not be realized. The ultimate realization of DTAs is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income, and tax-planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the DTAs are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences or tax carryforwards as of June 30, 2019 except for the AMT credit carryforward.

The Tax Cuts and Jobs Act was signed into law on December 22, 2017. The Tax Act reduced the U.S. federal corporate tax rate from 35% to 21%, effective January 1, 2018. The Tax Act repeals the AMT for corporations, and permits any existing AMT credit carryforwards to be used to reduce the regular tax obligation in 2018, 2019 and 2020. Companies may continue using AMT credits to offset any regular income tax liability in years 2018 through 2020, with 50% 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, 50% of the $1.2 million AMT credit carryforwards are included in prepaid and other current assets, and the remaining AMT credit carryforwards are included in noncurrent assets in the consolidated balance sheets as of June 30, 2019 and December 31, 2018.

Current accounting standards include guidance on the accounting for uncertainty in income taxes recognized in the financial statements. Such standards also prescribe a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company believes that the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of June 30, 2019 or December 31, 2018 and we do not expect any significant changes in the next twelve months. Should we need to accrue interest or penalties on uncertain tax positions, we would recognize the interest as interest expense and the penalties as a selling, general and administrative expense. As of June 30, 2019, tax years 2015-2018 remained subject to examination by federal and state tax authorities.

As of June 30, 2019, we had approximately $130.9 million of federal and $20.3 million of state net operating loss carryforwards, as well as approximately $8.7 million of federal Research and Development ("R&D") credit carryforwards.

15. Segments

We report information about our operating segments using the "management approach" in accordance with current accounting standards. This information is based on the way management organizes and reports the segments within the enterprise for making operating decisions and assessing performance. Our reportable segments are identified based on differences in products, services and markets served. There were no inter-segment sales. We manage our business based on two primary types of drug products: (i) diagnostic substances, including Tc 99m 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.

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

Three Months Ended June 30, 2019	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 5,940	$ —	$ —	$ 5,940
License revenue	9,953	—	—	9,953
Grant and other revenue	196,630	47,569	—	244,199
Total revenue	212,523	47,569	—	260,092
Cost of revenue	238	—	—	238
Research and development expenses	775,462	295,180	—	1,070,642
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	3,062	1,821,812	1,824,874
Depreciation and amortization (2)	—	—	36,726	36,726
Loss from operations (3)	(563,177)	(250,673)	(1,858,538)	(2,672,388)
Other expense (4)	—	—	(1,590)	(1,590)
Income tax benefit	35	16	117	168
Net loss from continuing operations	(563,142)	(250,657)	(1,860,011)	(2,673,810)
Income from discontinued operations, net of tax	632	—	—	632
Net loss	(562,510)	(250,657)	(1,860,011)	(2,673,178)
Total assets, net of depreciation and amortization:				
United States	$ 220,334	$ 11,235	$ 7,892,312	$ 8,123,881
International	6,514	—	—	6,514
Capital expenditures	—	—	—	—

Three Months Ended June 30, 2018	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 6,665	$ —	$ —	$ 6,665
License revenue	257,709	—	—	257,709
Grant and other revenue	156,889	120,864	—	277,753
Total revenue	421,263	120,864	—	542,127
Cost of revenue	35,392	—	—	35,392
Research and development expenses	913,158	229,560	—	1,142,718
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	16,630	1,735,258	1,751,888
Depreciation and amortization (2)	—	—	37,511	37,511
Loss from operations (3)	(527,287)	(125,326)	(1,772,769)	(2,425,382)
Other expense (4)	—	—	(20,719)	(20,719)
Income tax benefit	2,356	560	8,013	10,929
Net loss from continuing operations	(524,931)	(124,766)	(1,785,475)	(2,435,172)
Loss from discontinued operations, net of tax	(1,938)	—	—	(1,938)
Gain on sale of discontinued operations, net of tax	43,053	—	—	43,053
Net loss	(483,816)	(124,766)	(1,785,475)	(2,394,057)
Total assets, net of depreciation and amortization:				
United States	$ 409,769	$ 87,751	$ 8,139,434	$ 8,636,954
International	22,147	—	1,391	23,538
Capital expenditures	—	—	3,165	3,165

Six Months Ended June 30, 2019	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 9,090	$ —	$ —	$ 9,090
License revenue	9,953	—	—	9,953
Grant and other revenue	232,621	50,052	—	282,673
Total revenue	251,664	50,052	—	301,716
Cost of revenue	6,364	—	—	6,364
Research and development expenses	1,516,045	295,180	—	1,811,225
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	14,776	3,501,835	3,516,611
Depreciation and amortization (2)	—	—	73,505	73,505
Loss from operations (3)	(1,270,745)	(259,904)	(3,575,340)	(5,105,989)
Other income (4)	—	—	7,122	7,122
Provision for income tax	(177)	(36)	(495)	(708)
Net loss from continuing operations	(1,270,922)	(259,940)	(3,568,713)	(5,099,575)
Loss from discontinued operations, net of tax	(2,665)	—	—	(2,665)
Net loss	(1,273,587)	(259,940)	(3,568,713)	(5,102,240)
Total assets, net of depreciation and amortization:				
United States	$ 220,334	$ 11,235	$ 7,892,312	$ 8,123,881
International	6,514	—	—	6,514
Capital expenditures	—	—	—	—

Six Months Ended June 30, 2018	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	$ 7,460	$ —	$ —	$ 7,460
License revenue	257,709	—	—	257,709
Grant and other revenue	389,325	164,078	—	553,403
Total revenue	654,494	164,078	—	818,572
Cost of revenue	35,710	—	—	35,710
Research and development expenses	1,698,169	443,505	—	2,141,674
Selling, general and administrative expenses, excluding depreciation and amortization (1)	—	25,237	3,465,036	3,490,273
Depreciation and amortization (2)	—	—	75,498	75,498
Loss from operations (3)	(1,079,385)	(304,664)	(3,540,534)	(4,924,583)
Other expense (4)	—	—	(4,259,480)	(4,259,480)
Income tax benefit	1,284	363	9,282	10,929
Net loss from continuing operations	(1,078,101)	(304,301)	(7,790,732)	(9,173,134)
Loss from discontinued operations, net of tax	(1,938)	—	—	(1,938)
Gain on sale of discontinued operations, net of tax	43,053	—	—	43,053
Net loss	(1,036,986)	(304,301)	(7,790,732)	(9,132,019)
Total assets, net of depreciation and amortization:				
United States	$ 409,769	$ 87,751	$ 8,139,434	$ 8,636,954
International	22,147	—	1,391	23,538
Capital expenditures	—	—	3,165	3,165

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

(2) Depreciation and amortization is reflected in selling, general and administrative expenses ($36,726 and $37,511 for the three-month periods ended June 30, 2019 and 2018, and $73,505 and $75,498 for the six-month periods ended June 30, 2019 and 2018, respectively).

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

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

16. Supplemental Disclosure for Statements of Cash Flows

During the six-month periods ended June 30, 2019 and 2018, we paid interest aggregating $6,000 and $4,000, respectively. During the six-month periods ended June 30, 2019 and 2018, we issued 8,128 and 4,734 shares of our common stock as matching contributions to our 401(k) Plan which were valued at $20,000 and $36,000, respectively.

17. Subsequent Events

The Company has evaluated events and transactions subsequent to June 30, 2019 and through the date these consolidated financial statements were included in this Quarterly Report on Form 10-Q and filed with the SEC.

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:

- our history of operating losses and uncertainty of future profitability;
- the outcome of any pending litigation;
- 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;
- 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;
- 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," "plan," "expect," "future," "intend," "estimate," "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.

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

On April 2, 2018, the Company entered into an Amendment to the Asset Purchase Agreement. Pursuant to the Amendment, Cardinal Health 414 paid the Company approximately $6.0 million and agreed to pay the Company an amount equal to the unused portion of the letter of credit in favor of CRG (not to exceed approximately $7.1 million) promptly after the earlier of (i) the expiration of the letter of credit and (ii) the receipt by Cardinal Health 414 of evidence of the return and cancellation of the letter of credit. In exchange, the obligation of Cardinal Health 414 to make any further contingent payments has been eliminated. Cardinal Health 414 is still obligated to make the milestone payments in accordance with the terms of the earnout provisions of the Purchase Agreement. On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit.

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, and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by MT. See Note 15 to the 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.

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-constructs, MT-1002, which is designed to specifically target and kill activated CD206+ macrophages by delivering doxorubicin, and MT-2002, which is designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent. We have contracted with independent facilities to produce sufficient quantities of the MT-1002 and MT-2002 agents along with the concomitant analytical standards, to provide material for planned preclinical animal studies and future clinical trials.

Manocept Platform – Immuno-Diagnostics Clinical Data

Rheumatoid Arthritis

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

In 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 trials. In May 2019, we began enrolling patients in 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. The pivotal Phase 3 study program will assess joint disease status and monitor patient response to therapy.

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 I/II 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.

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.

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 is currently ongoing with expected completion in late 2019.

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.

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 two 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 progressing well.

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 class is designed to deplete activated macrophages via apoptosis. The MT-2000 class is designed to modulate activated macrophages from a classically activated phenotype to the alternatively activated phenotype. Both families have been tested in a number of disease models in rodents.

We 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).

Nonalcoholic Fatty Liver Disease ("NAFLD")

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

Other Immunotherapeutic Applications

We have completed an expanded series of predictive *in vitro* screening tests of the MT-1002 and MT-2002 therapeutic conjugates against the Zika and Dengue viruses, which included infectivity and viral replication inhibition effectiveness as well as dose finding studies and mechanisms of action, the latter based on conjugate structures. We have also completed a series of predictive *in vivo* screening tests of the MT-1002 and MT-2002 therapeutic conjugates against Leishmaniosis, which included host cell targeting and killing effectiveness as well as dose finding studies and mechanisms of action. A portion of the results from the *in vivo* Leishmaniosis study, completed in conjunction with the National Institute of Allergy and Infectious Diseases/NIH, was recently published in the *Journal of Experimental Medicine* (published in the circulated version *Journal of Experimental Medicine* 2018 Jan 2;215(1):357-375). The results from all evaluations were positive and have provided a basis for moving forward with additional *in vivo* testing of the selected conjugates. We have selected collaborators for these *in vivo* studies, and we will provide updates as information becomes available on future testing.

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

Outlook

Our operating expenses in recent years have been focused primarily on support of both diagnostic and therapeutic applications of our Manocept platform, and Tc99m tilmanocept. We incurred approximately $1.8 million and $2.1 million in total on research and development activities during the six-month periods ended June 30, 2019 and 2018, respectively. Of the total amounts we spent on research and development during those periods, excluding costs related to our internal research and development headcount and our general and administrative staff which we do not currently allocate among the various development programs that we have underway, we incurred out-of-pocket charges by program as follows:

	Six Months Ended June 30,	
Development Program [(a)]	**2019**	**2018**
Manocept Platform - Diagnostics [(b)]	$ 825,520	$ 604,619
Manocept Platform - Therapeutics [(b)]	295,180	565,364
Tc99m Tilmanocept	8,514	144,141

(a) Certain development program expenditures were offset by grant reimbursement revenues totaling $265,000 and $511,000 during the six-month periods ended Jun 30, 2019 and 2018, respectively.
(b) Certain 2018 Manocept Platform amounts have been reclassified from Diagnostics to Therapeutics to conform to 2019 presentation.

The divestiture of NAV4694 decreased our development costs over the past year, however we expect our total research and development expenses, including out-of-pocket charges as well as internal headcount and support costs, to be higher in 2019 than in 2018.

Tc99m tilmanocept is approved by the European Medicines Agency for use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity in the EU. We anticipate that we will incur costs 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.

We expect to focus the majority of our efforts on the advancement of our efforts with our Manocept platform. In the near term, we have begun or plan to begin three clinical studies in RA during the course of 2019 and complete those clinical trials by the end of 2020.

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.

Discontinued Operations

In March 2017, Navidea completed the Asset Sale to Cardinal Health 414, as discussed previously under "The Company." On April 2, 2018, the Company entered into an Amendment to the Asset Purchase Agreement. Pursuant to the Amendment, Cardinal Health 414 paid the Company approximately $6.0 million and agreed to pay the Company an amount equal to the unused portion of the letter of credit in favor of CRG (not to exceed approximately $7.1 million) promptly after the earlier of (i) the expiration of the letter of credit and (ii) the receipt by Cardinal Health 414 of evidence of the return and cancellation of the letter of credit. In exchange, the obligation of Cardinal Health 414 to make any further contingent payments has been eliminated. Cardinal Health 414 is still obligated to make the milestone payments in accordance with the terms of the earnout provisions of the Purchase Agreement. On April 9, 2018, CRG drew approximately $7.1 million on the letter of credit.

Results of Operations

Our pharmaceutical product candidates are not yet generating commercial revenue, therefore 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 June 30, 2019 and 2018

License Revenue. During the second quarters of 2019 and 2018, we recognized license revenue of $10,000 and $258,000, respectively, related to the sublicense of NAV4694 to Meilleur, including a non-refundable upfront payment in 2018.

Grant and Other Revenue. During the second quarter of 2019, we recognized $244,000 of grant and other revenue as compared to $278,000 during the same period in 2018. Grant revenue of $244,000 and $278,000 during the second quarters of 2019 and 2018, respectively, was related to SBIR grants from the NIH supporting Manocept development. No other revenue was recognized during the second quarters of 2019 and 2018.

Research and Development Expenses. Research and development expenses decreased $72,000, or 6%, to $1.0 million during the second quarter of 2019 from $1.1 million during the same period in 2018. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased Manocept therapeutic development costs of $158,000 including decreased clinical development and regulatory consulting costs, offset by increased manufacturing-related activities; (ii) decreased Tc99m tilmanocept development costs of $30,000 including decreased license fees; and (iii) decreased NAV4694 development costs of $9,000 including decreased clinical development costs; offset by (iv) increased Manocept diagnostic development costs of $205,000 including increased license fees, manufacturing-related activities and clinical trial costs. The net decrease in research and development expenses also included decreased compensation including incentive-based awards of $82,000 related to net decreased salaries and headcount.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $72,000, or 4%, to $1.9 million during the second quarter of 2019 from $1.8 million during the same period in 2018. Increased legal and professional services of $310,000, primarily related to the Goldberg litigation, and increased investor relations costs of $15,000 were offset by decreased compensation of $211,000.

Other Income (Expense). Other expense, net, was $2,000 during the second quarter of 2019 as compared to other expense, net of $21,000 during the same period in 2018. During the second quarter of 2018, we recorded non-cash interest expense of $43,000 related to interest that was compounded and added to the principal balance of the Platinum debt. During the second quarters of 2019 and 2018, we recognized interest income of $4,000 and $21,000, respectively.

Six Months Ended June 30, 2019 and 2018

License Revenue. During the first six months of 2019 and 2018, we recognized license revenue of $10,000 and $258,000, respectively, related to the sublicense of NAV4694 to Meilleur, including a non-refundable upfront payment in 2018.

Grant and Other Revenue. During the first six months of 2019, we recognized $283,000 of grant and other revenue as compared to $553,000 in the first six months of 2018. Grant revenue of $265,000 and $511,000 during the first six months of 2019 and 2018, respectively, was related to SBIR grants from the NIH supporting Manocept development. Other revenue of $18,000 and $43,000 during the first six months of 2019 and 2018, respectively, was related to development work performed at the request of our European marketing partner.

Research and Development Expenses. Research and development expenses decreased $330,000, or 15%, to $1.8 million during the first six months of 2019 from $2.1 million during the same period in 2018. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased Manocept therapeutic development costs of $270,000 including decreased clinical development and regulatory consulting costs, offset by increased manufacturing-related activities; (ii) decreased Tc99m tilmanocept development costs of $136,000 including decreased manufacturing-related activities and license fees; and (iii) decreased NAV4694 development costs of $34,000 including decreased clinical development costs; offset by (iv) increased Manocept diagnostic development costs of $221,000 including increased manufacturing-related activities and license fees offset by decreased clinical trial costs. The net decrease in research and development expenses also included decreased compensation including incentive-based awards of $124,000 related to net decreased salaries and headcount.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were approximately $3.6 million during the first six months of 2019 and 2018. Increased legal and professional services of $495,000, primarily related to the Goldberg litigation, were offset by decreased compensation of $330,000 and decreased investor relations costs of $32,000.

Other Income (Expense). Other income, net, was $7,000 during the first six months of 2019 as compared to other expense, net of $4.3 million during the same period in 2018. We recorded a loss on extinguishment of the CRG debt of $4.3 million during the first six months of 2018. During the first six months of 2019 and 2018, we recognized interest income of $17,000 and $97,000, respectively. Interest income in the first six months of 2018 was primarily related to the guaranteed consideration due from Cardinal Health 414, which was discounted to present value at the closing date of the Asset Sale. For the first six months of 2018, we recorded non-cash interest expense of $85,000 related to interest that was compounded and added to the principal balance of the Platinum debt.

Liquidity and Capital Resources

Cash balances increased to $5.1 million at June 30, 2019 from $3.5 million at December 31, 2018. The net increase was primarily due to proceeds from issuance of common stock of $6.0 million and sales and maturities of available-for-sale securities of $600,000, offset by cash used to fund our operations of $4.3 million, stock issuance costs of $572,000, and payments on notes payable of $236,000.

Operating Activities. Cash used in operations was $4.3 million during the first six months of 2019 compared to $8.3 million provided during the same period in 2018.

Accounts receivable increased to $207,000 at June 30, 2019 from $21,000 at December 31, 2018, primarily due to increased grant reimbursements receivable of $201,000.

Prepaid expenses and other current assets decreased to $1.0 million at June 30, 2019 from $1.3 million at December 31, 2018, primarily due to normal amortization of prepaid insurance.

Accounts payable increased to $673,000 at June 30, 2019 from $425,000 at December 31, 2018, primarily driven by net increased payables due for Manocept development costs, offset by decreased payables due for legal and professional services. Accrued liabilities and other current liabilities decreased to $2.3 million at June 30, 2019 from $2.5 million at December 31, 2018, primarily related to decreased accruals for compensation, offset by increased accruals for legal and professional services. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our development activity related to the Manocept platform.

Investing Activities. Investing activities provided $627,000 during the first six months of 2019 compared to $997,000 during the same period in 2018. Sales of available-for-sale securities provided $400,000 and $200,000 during the first six months of 2019 and 2018, respectively. Maturities of available-for-sale securities provided $200,000 and $800,000 during the first six months of 2019 and 2018, respectively.

Financing Activities. Financing activities provided $5.2 million during the first six months of 2019 compared to using $7.4 million during the same period in 2018. The $5.2 million provided by financing activities in the first six months of 2019 consisted primarily of proceeds from issuance of common stock of $6.0 million, offset by stock issuance costs of $572,000 and principal payments on financed insurance premiums of $236,000. The $7.4 million used by financing activities in the first six months of 2018 consisted primarily of CRG's draw on the letter of credit of $7.1 million and principal payments on financed insurance premiums of $238,000.

Public Offering

See Notes 2 and 12 to the accompanying consolidated financial statements.

Private Placement

See Notes 2 and 12 to the accompanying consolidated financial statements.

CRG Litigation

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

Platinum Litigation

See Notes 2, 9 and 11 to the accompanying consolidated financial statements.

Goldberg Agreement and Litigation

See Notes 2, 7 and 11 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 monetize our investment in non-core technologies, our ability to obtain milestone or development funds from potential development and distribution partners, regulatory actions by the FDA and international regulatory bodies, the ability to procure required financial resources, the outcome of any pending litigation, and intellectual property protection.

We plan to focus our resources during the remainder of 2019 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 time lines, 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 CRG, Platinum and Dr. Goldberg. 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 recent public offering provided gross proceeds of $6.0 million for additional working capital. 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. See Note 2 to the accompanying consolidated financial statements.

Off-Balance Sheet Arrangements

As of June 30, 2019, we had no off-balance sheet arrangements.

Recent Accounting Standards

See Note 1(d) 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.

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 December 31, 2018, 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, who serves as our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer, understands that our disclosure controls and procedures do not guarantee that all errors and all improper conduct will be prevented. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, a design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments and decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons, or by management override of the control. Further, the design of any system of controls is also based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations of a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

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

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

Changes in Control Over Financial Reporting

During the quarter ended June 30, 2019, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

See Note 11 to the accompanying 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, 2018, filed with the SEC on March 15, 2019.

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)
August 9, 2019

By: /s/ Jed A. Latkin

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

Exhibit 31.1

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

I, Jed A. Latkin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Navidea Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 9, 2019

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

Exhibit 32.1

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

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

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

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

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

August 9, 2019

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