

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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

State or Other Jurisdiction of
Incorporation or Organization

31-1080091

IRS Employer Identification No.

4995 Bradenton Avenue, Suite 240, Dublin, Ohio

Address of Principal Executive Offices

43017-3552

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 12b-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: 10,052,322 shares of common stock, par value \$.001 per share (as of the close of business on May 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**

	March 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,470,442	\$ 3,475,881
Available-for-sale securities	600,228	799,270
Accounts and other receivables	9,868	21,151
Prepaid expenses and other	1,149,793	1,299,454
Total current assets	<u>3,230,331</u>	<u>5,595,756</u>
Property and equipment	1,212,089	1,251,185
Less accumulated depreciation and amortization	1,106,155	1,089,013
Property and equipment, net	<u>105,934</u>	<u>162,172</u>
Right-of-use lease assets	406,842	—
Less accumulated amortization	39,400	—
Right-of-use lease assets, net	<u>367,442</u>	<u>—</u>
License agreements, patents and trademarks	480,404	480,404
Less accumulated amortization	59,328	51,912
License agreements, patents and trademarks, net	<u>421,076</u>	<u>428,492</u>
Other assets	834,977	835,107
Total assets	<u>\$ 4,959,760</u>	<u>\$ 7,021,527</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 852,612	\$ 424,718
Accrued liabilities and other	2,122,745	2,517,047
Notes payable	198,798	316,074
Lease liabilities, current	241,985	—
Terminated lease liability, current	—	120,679
Total current liabilities	<u>3,416,140</u>	<u>3,378,518</u>
Lease liabilities	685,985	—
Terminated lease liability	—	468,494
Deferred revenue	700,000	700,000
Other liabilities	63,000	64,055
Total liabilities	<u>4,865,125</u>	<u>4,611,067</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock; \$.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock; \$.001 par value; 300,000,000 shares authorized; 10,052,392 and 10,019,535 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	201,048	200,391
Additional paid-in capital	338,377,004	338,265,383
Accumulated deficit	(339,151,954)	(336,722,905)
Accumulated other comprehensive gain (loss)	228	(730)
Total Navidea stockholders' (deficit) equity	<u>(573,674)</u>	<u>1,742,139</u>
Noncontrolling interest	668,309	668,321
Total stockholders' equity	<u>94,635</u>	<u>2,410,460</u>
Total liabilities and stockholders' equity	<u>\$ 4,959,760</u>	<u>\$ 7,021,527</u>

See accompanying notes to consolidated financial statements.

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

	Three Months Ended	
	March 31,	
	2019	2018
Revenue:		
Royalty revenue	\$ 3,150	\$ 795
Sublease revenue	94,408	—
Grant and other revenue	38,474	275,650
Total revenue	<u>136,032</u>	<u>276,445</u>
Cost of revenue	6,126	318
Gross profit	<u>129,906</u>	<u>276,127</u>
Operating expenses:		
Research and development	740,583	998,956
Selling, general and administrative	1,822,924	1,776,372
Total operating expenses	<u>2,563,507</u>	<u>2,775,328</u>
Loss from operations	<u>(2,433,601)</u>	<u>(2,499,201)</u>
Other income (expense):		
Interest income, net	9,848	31,387
Loss on extinguishment of debt	—	(4,265,434)
Other, net	(1,135)	(4,714)
Total other income (expense), net	<u>8,713</u>	<u>(4,238,761)</u>
Loss before income taxes	<u>(2,424,888)</u>	<u>(6,737,962)</u>
Provision for income taxes	(876)	—
Net loss from continuing operations	<u>(2,425,764)</u>	<u>(6,737,962)</u>
Loss from discontinued operations, net of tax effect	<u>(3,297)</u>	<u>—</u>
Net loss	<u>(2,429,061)</u>	<u>(6,737,962)</u>
Less loss attributable to noncontrolling interest	<u>(12)</u>	<u>(9)</u>
Net loss attributable to common stockholders	<u>\$ (2,429,049)</u>	<u>\$ (6,737,953)</u>
Loss per common share (basic and diluted):		
Continuing operations	\$ (0.24)	\$ (0.83)
Discontinued operations	\$ —	\$ —
Attributable to common stockholders	\$ (0.24)	\$ (0.83)
Weighted average shares outstanding	10,017,848	8,113,451

See accompanying notes to consolidated financial statements.

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

	Three Months Ended	
	March 31,	
	2019	2018
Net loss	\$ (2,429,061)	\$ (6,737,962)
Unrealized gain (loss) on available-for-sale securities	958	(176)
Comprehensive loss	<u>\$ (2,428,103)</u>	<u>\$ (6,738,138)</u>

See accompanying notes to consolidated financial statements.

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

For the Three Months Ended March 31, 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	<u>10,052,392</u>	<u>\$ 201,048</u>	<u>\$ 338,377,004</u>	<u>\$ (339,151,954)</u>	<u>\$ 228</u>	<u>\$ 668,309</u>	<u>\$ 94,635</u>

For the Three Months Ended March 31, 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	<u>8,147,986</u>	<u>\$ 162,960</u>	<u>\$ 331,467,199</u>	<u>\$ (327,346,921)</u>	<u>\$ (2,572)</u>	<u>\$ 668,691</u>	<u>\$ 4,949,357</u>

See accompanying notes to consolidated financial statements.

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

	Three Months Ended	
	March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (2,429,061)	\$ (6,737,962)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	36,779	37,987
Compounded interest on long term debt	—	41,624
Stock compensation expense	61,978	137,964
Loss on extinguishment of debt	—	4,265,434
Value of stock issued to employees	—	165,021
Value of stock issued to 401(k) plan for employer matching contributions	—	35,980
Changes in operating assets and liabilities:		
Accounts and other receivables	11,283	(7,749)
Prepaid expenses and other assets	(217,651)	50,805
Accounts payable	427,894	(154,811)
Accrued and other liabilities	(68,500)	(79,109)
Deferred revenue	11,940	(15,037)
Net cash used in operating activities	<u>(2,165,338)</u>	<u>(2,259,853)</u>
Cash flows from investing activities:		
Maturities of available-for-sale securities	200,000	400,000
Proceeds from return of equipment	26,875	—
Net cash provided by investing activities	<u>226,875</u>	<u>400,000</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	50,300	200
Principal payments on notes payable	(117,276)	(118,337)
Net cash used in financing activities	<u>(66,976)</u>	<u>(118,137)</u>
Net decrease in cash and cash equivalents	<u>(2,005,439)</u>	<u>(1,977,990)</u>
Cash and cash equivalents, beginning of period	3,475,881	2,795,006
Cash and cash equivalents, end of period	<u>\$ 1,470,442</u>	<u>\$ 817,016</u>

See accompanying notes to consolidated financial statements.

Notes to the Consolidated Financial Statements (unaudited)

1. Summary of Significant Accounting Policies

- a. **Basis of Presentation:** The information presented as of March 31, 2019 and for the three-month periods ended March 31, 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 March 31, 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 18, 2019, the Company’s Board of Directors approved a one-for-twenty reverse stock split of its issued and outstanding shares of common stock, effective at 12:01 am Eastern Time on April 26, 2019. 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. See Note 17.

- 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 March 31, 2019 and December 31, 2018 primarily consisted of the face amount of the notes plus accrued interest. At March 31, 2019, the fair value of our notes payable was approximately \$199,000, equal to the carrying value of \$199,000. 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 March 31, 2019 and December 31, 2018 were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of March 31, 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 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 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. It is not known at this time whether the court will hold oral argument on the appeal or when the court will render its decision. See Notes 9 and 11.

In addition, the Company is engaged in litigation with our former President and Chief Executive Officer, Dr. Michael Goldberg. During the first quarter of 2019, Navidea and MT filed complaints against Dr. Goldberg in New York and Delaware courts, and Dr. Goldberg filed a complaint against Navidea and MT in New York. See Notes 7 and 11.

On March 22, 2019, the Company entered into a Stock Purchase Agreement with John K. Scott, Jr. (the "Investor"), pursuant to which the Company will 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, par value \$0.001 per share (the "Common Stock"). The Company plans to use the proceeds from the Private Placement for general working capital purposes, including, without limitation, research and development, and other operating expenses. See Note 12.

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 Private Placement provides for up to \$3.0 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 therapeutic applications of our Manocept platform and all development programs undertaken by MT. 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 new 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 new 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 March 31, 2019 and 2018, the Company recognized revenue from contracts with customers of approximately \$14,000 and \$16,000. During the three-month periods ended March 31, 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 periods ended March 31, 2019 and 2018.

Three Months Ended March 31, 2019	Diagnostics
Royalty revenue:	
Europe	\$ 3,150
Other revenue:	
Additional stability studies	\$ 11,024
Three Months Ended March 31, 2018	Diagnostics
Royalty revenue:	
Europe	\$ 795
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 March 31, 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 periods ended March 31, 2019 and 2018.

	Three Months Ended March 31,	
	2019	2018
Total deferred revenue, beginning of period	\$ 711,024	\$ 26,061
Impact of adoption of ASU 2014-09 and related standards	—	700,000
Revenue recognized from satisfaction of performance obligations	(11,024)	(15,037)
Total deferred revenue, end of period	<u>\$ 700,000</u>	<u>\$ 711,024</u>

The Company had trade receivables of approximately \$1,000 and \$12,000 outstanding as of March 31, 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 new 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 and the NIH do not have a vendor-customer relationship and the grant awards are outside the scope of the new revenue recognition standard. Accordingly, the new revenue recognition standard need not be applied to 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 March 31, 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 March 31, 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	\$ —	\$ 600,228	\$ —	\$ 600,228
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 three-month periods ended March 31, 2019 and 2018. There were no transfers in or out of our Level 1 or Level 2 liabilities during the three-month periods ended March 31, 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 three-month periods ended March 31, 2019 and 2018.

5. Stock-Based Compensation

For the three-month periods ended March 31, 2019 and 2018, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately \$62,000 and \$138,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2019 and 2018.

A summary of the status of our stock options as of March 31, 2019, and changes during the three-month period then ended, is presented below.

	Three Months Ended March 31, 2019			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	157,908	\$ 24.82		
Granted	95,250	5.89		
Exercised	—	—		
Canceled and Forfeited	(5,300)	8.93		
Expired	(350)	11.00		
Outstanding at end of period (in years)	247,508	\$ 17.90	7.7	\$ —
Exercisable at end of period (in years)	84,175	\$ 34.35	4.8	\$ —

A summary of the status of our unvested restricted stock as of March 31, 2019, and changes during the three-month period then ended, is presented below.

	Three Months Ended March 31, 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 March 31, 2019, there was approximately \$166,000 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 1.1 years.

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 three-month periods ended March 31, 2019 and 2018 excludes the effects of 902,050 and 954,612 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 12,500 shares of unvested restricted stock for the three-month periods ended March 31, 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, the 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, 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 10, 2019, Dr. Goldberg answered the complaint and asserted counterclaims against Navidea for breach of contract related to the Platinum Note, for tortious interference, and for breach of contract, fraud in the inducement, mutual mistake of fact, unilateral mistake of fact, negligent misrepresentation, breach of the implied covenant of good faith and fair dealing, a declaratory judgment, and injunctive relief in connection with the Agreement. 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.

Also on February 20, 2019, MT initiated a suit against Dr. Goldberg in the Court of Chancery of the State of Delaware, alleging, among other things, breach of fiduciary duty as a director and officer of MT and conversion, and to obtain a declaratory judgment that the transactions Dr. Goldberg caused MT to enter into are void. On March 13, 2019, the Court of Chancery entered an order maintaining status quo, which provided, among other things, that MT's board of directors may authorize any act or transaction on behalf of the Company, and that without prior written authorization of the MT board, Dr. Goldberg shall not hold himself out as CEO of MT or purport to act or authorize any action on behalf of MT except as authorized by the MT board.

On March 7, 2019, Dr. Goldberg filed a complaint against Navidea and MT in the United States District Court for the Southern District of New York. The complaint alleges a breach of contract claim against both Navidea and MT for failure to pay to Dr. Goldberg funds allegedly due to him under the Platinum Note. The complaint further alleges a breach of contract claim against Navidea due to Navidea's failure to issue 1,175,000 shares to Dr. Goldberg, to issue MT super voting common stock, by removing Dr. Greene from the MT board of directors, by appointing Mr. Rice and Dr. Bruck to the MT board of directors, and by terminating Dr. Goldberg as CEO of MT. On April 26, 2019, Navidea moved to dismiss the claims related to the Platinum Note and MT filed an answer to the complaint. See Note 11.

8. Accounts Payable, Accrued Liabilities and Other

Accrued liabilities and other at March 31, 2019 and December 31, 2018 includes an aggregate of \$184,000 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 three-month period ended March 31, 2018, \$42,000 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 \$4,000 and \$2,000 during the three-month periods ended March 31, 2019 and 2018, respectively. The balance of the IPFS note was approximately \$199,000 and \$316,000 as of March 31, 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 March 31, 2019 and 2018, we recorded interest expense of \$4,000 and \$44,000, respectively, related to our notes payable. Of these amounts, \$0 and \$42,000 was compounded and added to the balance of our notes payable during the three-month periods ended March 31, 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	<u>\$ 406,842</u>	<u>\$ 998,602</u>	<u>\$ —</u>	<u>\$ —</u>

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 \$66,000 for the three-month period ended March 31, 2019. Sublease revenue was \$94,000 for the three-month period ended March 31, 2019.

The following table presents information about the amount, timing and uncertainty of cash flows arising from the Company's operating leases as of March 31, 2019.

Maturity of Lease Liabilities	Operating Lease Payments
2019 (remaining)	\$ 241,915
2020	319,034
2021	306,781
2022	253,339
Total undiscounted operating lease payments	1,121,069
Less imputed interest	193,099
Present value of operating lease liabilities	<u>\$ 927,970</u>
Balance Sheet Classification	
Current lease liabilities	\$ 241,985
Noncurrent lease liabilities	685,985
Total operating lease liabilities	<u>\$ 927,970</u>
Other Information	
Weighted-average remaining lease term for operating leases (in years)	3.4
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 \$97,000 during the three-month period ended March 31, 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 is currently appealing the Texas Court's judgment. The appeal is fully briefed and the parties await the court of appeals' ruling.

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

The Company has also been engaged in ongoing litigation with CRG in the Court of Common Pleas of Franklin County, Ohio (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, discovery is ongoing in the case and it is anticipated that the Company will file a Motion for Summary Judgment sometime in 2019.

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 United States Court of Appeals for 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. It is not known at this time whether the Second Circuit will hold oral argument on this matter or when the Second Circuit will render its decision. 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 an agreement (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 United States District Court for the Southern District of New York, 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 10, 2019, Dr. Goldberg answered the complaint and asserted counterclaims against Navidea for breach of contract related to the Platinum Note, for tortious interference, and for breach of contract, fraud in the inducement, mutual mistake of fact, unilateral mistake of fact, negligent misrepresentation, breach of the implied covenant of good faith and fair dealing, a declaratory judgment, and injunctive relief in connection with the Agreement. 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.

Also on February 20, 2019, MT initiated a suit against Dr. Goldberg in the Court of Chancery of the State of Delaware, alleging, among other things, breach of fiduciary duty as a director and officer of MT and conversion, and to obtain a declaratory judgment that the transactions Dr. Goldberg caused MT to enter into are void. On March 13, 2019, the Court of Chancery entered an order maintaining status quo, which provided, among other things, that MT’s board of directors may authorize any act or transaction on behalf of the Company, and that without prior written authorization of the MT board, Dr. Goldberg shall not hold himself out as CEO of MT or purport to act or authorize any action on behalf of MT except as authorized by the MT board.

On March 7, 2019, Dr. Goldberg filed a complaint against Navidea and MT in the United States District Court for the Southern District of New York. The complaint alleges a breach of contract claim against both Navidea and MT for failure to pay to Dr. Goldberg funds allegedly due to him under the Platinum Note. The complaint further alleges a breach of contract claim against Navidea due to Navidea’s failure to issue 1,175,000 shares to Dr. Goldberg, to issue MT super voting common stock, by removing Dr. Greene from the MT board of directors, by appointing Mr. Rice and Dr. Bruck to the MT board of directors, and by terminating Dr. Goldberg as CEO of MT. On April 26, 2019, Navidea moved to dismiss the claims related to the Platinum Note and MT filed an answer to the complaint. 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.

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.

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 is 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. The Staff initially granted Navidea a plan period through February 14, 2019 to regain compliance with Section 1003(f)(v) by effecting a reverse stock split or otherwise demonstrating sustained price improvement.

On January 28, 2019, the Company received a notice from the NYSE American that they had granted the Company an extension until March 31, 2019 to regain compliance with Section 1003(f)(v) of the NYSE American’s continued listing standards, and on March 22, 2019, Navidea announced that it was in discussions with the NYSE American regarding the timing of a potential reverse stock split later than March 31, 2019.

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 advised that the Company must provide the NYSE American with a plan to regain compliance with the price standard by April 15, 2019 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.

As previously disclosed, at the Company’s Annual Meeting of Stockholders held on August 16, 2018, the Company’s stockholders approved a proposal authorizing the Company’s Board of Directors to effect a reverse stock split by a ratio of not less than one-for-five and not more than one-for-twenty. On April 18, 2019, the Company’s Board of Directors approved a one-for-twenty reverse stock split of its issued and outstanding shares of common stock, effective at 12:01 am Eastern Time on April 26, 2019. Shares of the Company’s common stock began trading on a split-adjusted basis when the NYSE American market opened on that date. The reverse stock split was effected as part of the Company’s plan to regain compliance with the \$0.20 minimum bid price continued listing requirement of the NYSE American. See Note 17.

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 the Stock Purchase Agreement with the Investor, pursuant to which the Company will issue to the Investor in a Private Placement up to \$3.0 million in shares of the Company’s Common Stock. The Private Placement will 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 will 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 will not be later than June 15, 2019 (each, a “Subsequent Closing”, with each of the Initial Closing and any Subsequent Closing being a “Closing”), such amount of Securities agreed upon by the Company and the Investor, at a per share price to be determined in good faith by the Company and the Investor which price may be less than the greater of book or market value of one share of Common Stock within the meaning of the NYSE American standards; provided, that the total amount of Securities sold at any Subsequent Closing shall not exceed (i) \$3.0 million worth of the Securities less the aggregate purchase price paid by the Investor to the Company for any Securities purchased at any prior Closing, (ii) the number of shares that may be issued without violating the rules and regulations of the NYSE American, and (iii) the amount of shares that would result in the beneficial ownership in the Company by the Investor and his affiliates being equal to or less than 33.0% of the then issued and outstanding shares of Common Stock. The Company plans to use the proceeds from the Private Placement for general working capital purposes, including, without limitation, research and development, and other operating expenses. See Note 2.

During the three-month periods ended March 31, 2018, we issued 22,920 shares of our common stock valued at \$165,000 to our employees as partial payment in lieu of cash for their 2017 bonuses.

During the three-month period ended March 31, 2018, we issued 4,734 shares of our common stock as matching contributions to our 401(k) Plan which were valued at \$36,000.

13. Stock Warrants

At March 31, 2019, there are 818,000 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 \$22.98 per share. The warrants have remaining outstanding terms ranging from five months to 16.5 years.

In addition, at March 31, 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 March 31, 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 March 31, 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 March 31, 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 March 31, 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 March 31, 2019, tax years 2015-2018 remained subject to examination by federal and state tax authorities.

As of March 31, 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 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 and all development programs undertaken by MT.

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

Three Months Ended March 31, 2019	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	\$ 3,150	\$ —	\$ —	\$ 3,150
Sublease revenue	—	—	94,408	94,408
Grant and other revenue	35,991	2,483	—	38,474
Total revenue	39,141	2,483	94,408	136,032
Cost of revenue	6,126	—	—	6,126
Research and development expenses	740,583	—	—	740,583
Selling, general and administrative expenses, excluding depreciation and amortization ⁽¹⁾	—	11,714	1,774,431	1,786,145
Depreciation and amortization ⁽²⁾	—	—	36,779	36,779
Loss from operations ⁽³⁾	(707,568)	(9,231)	(1,716,802)	(2,433,601)
Other income ⁽⁴⁾	—	—	8,713	8,713
Provision for income taxes	(256)	(3)	(617)	(876)
Net loss from continuing operations	(707,824)	(9,234)	(1,708,706)	(2,425,764)
Loss from discontinued operations, net of tax	(3,297)	—	—	(3,297)
Net loss	(711,121)	(9,234)	(1,708,706)	(2,429,061)
Total assets, net of depreciation and amortization:				
United States	\$ 55,213	\$ 2,411	\$ 4,891,112	\$ 4,948,736
International	10,422	—	602	11,024
Capital expenditures	—	—	—	—
Three Months Ended March 31, 2018	Diagnostics	Therapeutics	Corporate	Total
Royalty revenue	\$ 795	\$ —	\$ —	\$ 795
Grant and other revenue	232,436	43,214	—	275,650
Total revenue	233,231	43,214	—	276,445
Cost of revenue	318	—	—	318
Research and development expenses	785,011	213,945	—	998,956
Selling, general and administrative expenses, excluding depreciation and amortization ⁽¹⁾	—	8,607	1,729,778	1,738,385
Depreciation and amortization ⁽²⁾	—	—	37,987	37,987
Loss from operations ⁽³⁾	(552,098)	(179,338)	(1,767,765)	(2,499,201)
Other expense ⁽⁴⁾	—	—	(4,238,761)	(4,238,761)
Net loss	(552,098)	(179,338)	(6,006,526)	(6,737,962)
Total assets, net of depreciation and amortization:				
United States	\$ 13,077,979	\$ 27,228	\$ 5,189,637	\$ 18,294,844
International	26,055	—	1,328	27,383
Capital expenditures	—	—	—	—

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

(2) Depreciation and amortization is reflected in selling, general and administrative expenses (\$36,779 and \$37,987 for the three-month periods ended March 31, 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 three-month periods ended March 31, 2019 and 2018, we paid interest aggregating \$4,000 and \$3,000, respectively. During the three-month period ended March 31, 2018, we issued 4,734 shares of our common stock as a matching contribution to our 401(k) Plan which were valued at \$36,000.

17. Subsequent Events

The Company has evaluated events and transactions subsequent to March 31, 2019 and through the date these consolidated financial statements were included in this Form 10-Q and filed with the SEC.

On April 18, 2019, the Company's Board of Directors approved a one-for-twenty reverse stock split of its issued and outstanding shares of common stock. The reverse split became effective at 12:01 am Eastern Time on April 26, 2019, and shares of the Company's common stock began trading on a split-adjusted basis when the NYSE American market opened on that date. The reverse stock split was effected as part of the Company's plan to regain compliance with the \$0.20 minimum bid price continued listing requirement of the NYSE American.

The Company's common stock continues to trade on the NYSE American under the trading symbol "NAVB," but now trades under the following new CUSIP number: 63937X202. 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 without any action on the part of the stockholders. 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 reverse stock split affected all issued and outstanding shares of the Company's common stock. In addition, the reverse split reduced the number of shares of common stock issuable upon the exercise of stock options or warrants outstanding immediately prior to the reverse split, and the number of shares reserved for future issuance under the Company's existing incentive compensation plan were proportionately reduced. The par value of the Company's common stock remains unchanged at \$0.001 per share after the reverse split. The reverse split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the reverse split resulted in some stockholders owning a fractional share as described below.

No fractional shares were issued in connection with the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share were instead entitled to receive a cash payment based on the closing price of the Company's common stock on April 25, 2019. Cash-in-lieu payments totaling approximately \$3,000 were made on May 6, 2019.

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;
- 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;
- the outcome of any pending litigation;
- our ability to comply with NYSE American continued listing standards; and
- other risk factors set forth in this report and detailed in our most recent Annual Report on Form 10-K and other SEC filings.

In addition, in this report, we use words such as “anticipate,” “believe,” “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.

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 were presented at the June 2018 SNMMI 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.

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 Phase 1/2 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, plans 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 would provide tilmanocept for use in this study. 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.

Macrophage Therapeutics Background

In December 2014, the Company formed a new business unit to further explore therapeutic applications for the Manocept platform. In January 2015, Navidea incorporated the business unit as MT, a majority-owned subsidiary of Navidea. MT has developed processes for producing the first two therapeutic Manocept immuno-constructs, MT-1002, designed to specifically target and kill activated CD206+ macrophages by delivering doxorubicin, and MT-2002, designed to inhibit the inflammatory activity of activated CD206+ macrophages by delivering a potent anti-inflammatory agent. MT has 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.

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

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

MT has been set up to pursue the therapeutic drug delivery model. This 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* STAMTM NASH model. We believe these agents present themselves as potential clinically effective candidates for further evaluation. We continue to use this model to further assess the activity of our agents.

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 Leishmaniasis, 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* Leishmaniasis 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, which we expect will take place over the next four to six months. 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 our Manocept platform, therapeutic product development, and Tc99m tilmanocept. We incurred approximately \$741,000 and \$999,000 in total on research and development activities during the three-month periods ended March 31, 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:

Development Program ^(a)	Three Months Ended March 31,	
	2019	2018
Manocept Platform ^(b)	\$ 205,160	\$ 189,279
Macrophage Therapeutics ^(b)	166,988	278,749
Tc99m Tilmanocept	9,750	115,122

(a) Certain development program expenditures were offset by grant reimbursement revenues totaling \$21,000 and \$233,000 during the three-month periods ended March 31, 2019 and 2018, respectively.

(b) Certain 2018 amounts have been reclassified from Manocept Platform to Macrophage 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 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

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

Three Months Ended March 31, 2019 and 2018

Sublease Revenue. During the first quarter of 2019, we recognized \$94,000 of sublease revenue from the sublease of our former headquarters. No sublease revenue was recognized during the first quarter of 2018. The increase is due to the new lease accounting standards which were effective January 1, 2019.

Grant and Other Revenue. During the first quarter of 2019, we recognized \$38,000 of grant and other revenue as compared to \$276,000 in the first quarter of 2018. Grant revenue of \$21,000 and \$233,000 during the first quarters of 2019 and 2018, respectively, was primarily related to SBIR grants from the NIH supporting Manocept development.

Research and Development Expenses. Research and development expenses decreased \$258,000, or 26%, to \$741,000 during the first quarter of 2019 from \$999,000 during the same period in 2018. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased therapeutics development costs of \$112,000 including decreased regulatory consulting costs and decreased clinical trial costs, offset by increased manufacturing-related activities; (ii) decreased Tc99m tilmanocept development costs of \$105,000 including decreased manufacturing-related activities; and (iii) decreased NAV4694 development costs of \$25,000 including decreased clinical development costs; offset by (iv) increased Manocept development costs of \$16,000 including increased manufacturing-related activities offset by decreased clinical trial costs. The net decrease in research and development expenses also included decreased compensation including incentive-based awards of \$42,000 related to net decreased salaries and headcount.

Selling, General and Administrative Expenses. Selling, general and administrative expenses remained steady at \$1.8 million during each of the first quarters of 2019 and 2018. Increased legal and professional services of \$185,000 and increased lease expenses of \$120,000 due to the new lease accounting standards which were effective January 1, 2019 were offset by decreased compensation of \$119,000 and decreased investor relations costs of \$47,000.

Other Income (Expense). Other income, net, was \$9,000 during the first quarter of 2019 as compared to other expense, net of \$4.2 million during the same period in 2018. We recorded a loss on extinguishment of the CRG debt of \$4.3 million during the first quarter of 2018. During the first quarters of 2019 and 2018, we recognized interest income of \$13,000 and \$76,000, respectively. Interest income in the first quarter 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 quarter of 2018, we recorded non-cash interest expense of \$42,000 related to interest that was compounded and added to the principal balance of the Platinum debt.

Liquidity and Capital Resources

Cash balances decreased to \$1.5 million at March 31, 2019 from \$3.5 million at December 31, 2018. The net decrease was primarily due to cash used to fund our operations of \$2.2 million and payments on notes payable of \$117,000, offset by maturities of available-for-sale securities of \$200,000 and proceeds from issuance of common stock of \$50,000.

Operating Activities. Cash used in operations was \$2.2 million during the first quarter of 2019 compared to \$2.3 million used during the same period in 2018.

Prepaid expenses and other current assets decreased to \$1.1 million at March 31, 2019 from \$1.3 million at December 31, 2018, primarily due to normal amortization of prepaid insurance.

Accounts payable increased to \$853,000 at March 31, 2019 from \$425,000 at December 31, 2018, primarily driven by net increased payables due for legal and professional services. Accrued liabilities and other current liabilities decreased to \$2.1 million at March 31, 2019 from \$2.5 million at December 31, 2018, primarily related to decreased accruals for compensation and Manocept development costs. Our payable and accrual balances will continue to fluctuate but will likely increase overall as we increase our development activity related to the Manocept platform.

Investing Activities. Investing activities provided \$227,000 during the first quarter of 2019 compared to \$400,000 during the same period in 2018. Maturities of available-for-sale securities provided \$200,000 and \$400,000 during the first quarters of 2019 and 2018, respectively.

Financing Activities. Financing activities used \$67,000 during the first quarter of 2019 compared to \$118,000 during the same period in 2018. The \$67,000 used by financing activities in the first quarter of 2019 consisted primarily of principal payments on financed insurance premiums of \$117,000, offset by proceeds from issuance of common stock of \$50,000. The \$118,000 used by financing activities in the first quarter of 2018 consisted primarily of principal payments on financed insurance premiums.

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 Private Placement provides for up to \$3.0 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. See Note 2 to the accompanying consolidated financial statements.

Off-Balance Sheet Arrangements

As of March 31, 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 March 31, 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

- 3.1 [Certificate of Amendment to Amended and Restated Certificate of Incorporation of Navidea Biopharmaceuticals, Inc. \(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed April 26, 2019\).](#)
- 10.1 [Stock Purchase Agreement, dated March 22, 2019, between Navidea Biopharmaceuticals, Inc. and John K. Scott, Jr.*](#)
- 31.1 [Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*](#)
- 32.1 [Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**](#)
- 101.INS XBRL Instance Document*
- 101.SCH XBRL Taxonomy Extension Schema Document*
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document*
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document*
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document*
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

** Furnished herewith.

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

SIGNATURES

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

NAVIDEA BIOPHARMACEUTICALS, INC.
(the Company)
May 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)

STOCK PURCHASE AGREEMENT

This Stock Purchase Agreement (this “*Agreement*”) is made and entered into as of March 22, 2019, by and between Navidea Biopharmaceuticals, Inc., a Delaware corporation (the “*Company*”), and John K. Scott Jr. (the “*Investor*”).

WHEREAS, the Company desires to sell to the Investor, and the Investor desire to purchase from the Company, up to \$3.0 million in shares (the “*Securities*”) of the Company’s common stock, par value \$0.001 per share (the “*Common Stock*”), subject to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual representations, warranties, covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Investor hereby agree as follows:

1. **Definitions.** As used in this Agreement, unless the context otherwise requires, the following terms shall have the respective meanings specified or referred to in this Section 1:

“*Affiliate*” means, when used with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, controls or is controlled by or is under common control with the Person specified. For purposes of this definition, “control,” when used with respect to any Person, means the power to direct the management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise. The terms “controlling” and “controlled” have meanings correlative to the foregoing.

“*Court Order*” means any judgment, order, award or decree of any foreign, federal, state, local or other court or administrative or regulatory body and any award in any arbitration proceeding.

“*Encumbrance*” means any lien (statutory or other), encumbrance, claim, charge, security interest, mortgage, deed of trust, pledge, hypothecation, assignment, conditional sale or other title retention agreement, preference, priority or other security agreement or preferential arrangement of any kind or nature, and any easement, encroachment, covenant, restriction, right of way, defect in title or other encumbrance of any kind.

“*Governmental Body*” means any foreign, federal, state, local or other government, governmental, statutory or administrative authority or regulatory body, self-regulatory organization or any court, tribunal or judicial or arbitral body.

“*Person*” means any individual, partnership, corporation, limited liability company, association, joint venture, joint-stock company, trust, unincorporated organization, Governmental Body or other entity.

“*Requirements of Law*” means any applicable foreign, federal, state and local laws, statutes, regulations, rules, codes, ordinances, Court Orders and requirements enacted, adopted, issued or promulgated by any Governmental Body or common law or any applicable consent decree or settlement agreement entered into with any Governmental Body.

“*SEC Reports*” means, collectively, all reports of the Company required to be filed by it under the Securities Act of 1933, as amended (the “*Securities Act*”) and the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), including pursuant to Section 13(a) or 15(d) thereof, for the twelve months preceding the date hereof. The term “SEC Reports” shall not include any proxy statement (or amendment or supplement thereto) filed or prepared by the Company.

2. **Purchases of Common Stock.**

(a) Subscription. Subject to the terms and conditions hereof, the Investor hereby irrevocably subscribes for the Securities for an aggregate purchase price of up to \$3,000,000, which is issuable and payable as described in Section 4. The Investor acknowledges that the Securities will be subject to restrictions on transfer as set forth in this Agreement.

(b) Compliance with NYSE American Rules. Notwithstanding anything in this Agreement to the contrary, unless permitted by the applicable rules and regulations of the NYSE American, the total number of shares of Common Stock that may be issued under this Agreement, shall not exceed the aggregate number of shares of Common Stock that the Company may issue without breaching the Company’s obligations under the rules or regulations of the NYSE American (the number of shares that may be issued without violating such rules and regulations, the “*NYSE Cap*”). Notwithstanding the foregoing, such limitation shall not apply in the event that the Company obtains the approval of its stockholders as required by the applicable rules of the NYSE American for issuances of shares of Common Stock in excess of such amount the NYSE Cap, and shall also be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. The Company may, in its sole discretion, determine whether to obtain stockholder approval to issue more shares of Common Stock hereunder than is permitted by the NYSE Cap if such issuance would require stockholder approval under the rules or regulations of the NYSE American.

(c) **Beneficial Ownership Limitation.** The Company shall not issue, and the Investor shall not purchase, any shares of Common Stock under this Agreement, if such shares proposed to be issued and sold, when aggregated with all other shares of Common Stock then owned beneficially (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder) by the Investor and its affiliates would result in the beneficial ownership by the Investor and its affiliates of more than 33.0% of the then issued and outstanding shares of Common Stock (such limitation being herein after referred to as the “**Beneficial Ownership Limitation**”).

3. **Use of Proceeds.** The Company intends to use the net proceeds received from the sale of the Securities or otherwise pursuant to this Agreement for general working capital purposes, including, without limitation, on product development and commercialization, development of intellectual property, purchases of inventory, sales and marketing, repayment of principal and interest on outstanding indebtedness, and other operating expenses.

4. **Payments; Closings.**

(a) **Initial Closing.** The initial closing of the sale and purchase of the Securities (the “**Initial Closing**”) shall occur on the date hereof or such other date and time agreed upon by the parties hereto (such date and time of delivery and full payment for the Securities being herein called, the “**Initial Closing Date**”). On the Initial Closing Date, the Company shall deliver to the Investor, and the Investor shall purchase, \$50,000.00 worth of the Securities at a per share price equal to the closing price or last sale price of a share of Common Stock reported on the NYSE American market for the business day immediately before the Initial Closing Date.

(b) **Subsequent Closings.** Subject to the limitations set forth in Sections 2(b) and 2(c) above, from time to time, on such date or dates to be determined by the Company and the Investor, which date shall not be later than June 15, 2019 (each a “**Subsequent Closing Date**”, with each of the Initial Closing Date and any Subsequent Closing Date being a “**Closing Date**”), Investor agrees to purchase, and the Company agrees to sell and issue to Investor (the closing of such subsequent sale and issuance, a “**Subsequent Closing**”, with each of the Initial Closing and any Subsequent Closing being a “**Closing**”), such amount of Securities agreed upon by the Company and the Investor, at a per share price to be determined in good faith by the Company and the Investor which price may be less than the greater of book or market value of one share of Common Stock within the meaning of the NYSE American standards (the aggregate amount paid by the Investor at any Closing being an “**Aggregate Purchase Price**”); provided, that the total amount of Securities sold at any Subsequent Closing shall not exceed (i) \$3.0 million worth of the Securities less the Aggregate Purchase Price paid by the Investor to the Company for any Securities purchased at any prior Closing, (ii) the NYSE Cap or (iii) the Beneficial Ownership Limitation.

(c) **Payment for Securities.** At each Closing, the Investor shall pay to the Company an amount equal to the applicable Aggregate Purchase Price payable at such Closing as full payment for the Securities issuable at such Closing via wire transfer of immediately available funds in accordance with the wiring instructions attached hereto as **Appendix A** or as otherwise designated by the Company, by check payable to the Company, or by any combination of such methods.

5. **Representations and Warranties of the Company.** As of the date hereof and as of each Closing Date, the Company represents and warrants that:

(a) **Organization.** The Company is duly incorporated or formed and validly existing and in good standing under the law of its jurisdiction of incorporation or formation. The Company is duly qualified and in good standing as a foreign company in each other jurisdiction in which it owns or leases property or in which the conduct of its business requires it to be so qualified or licensed, except where the failure to be so qualified and in good standing would not, individually or in the aggregate, have or reasonably be expected to have a material adverse effect on the business, properties, financial condition, results of operations, or prospects of the Company (a “**Material Adverse Effect**”).

(b) **Authorization.** The Company has all requisite power and authority to execute and deliver this Agreement and to perform its obligations hereunder in accordance with the terms hereof. The execution, delivery and performance of this Agreement by the Company have been duly authorized by all necessary corporate action. This Agreement has been duly executed and delivered by the Company, and this Agreement constitutes the legal, valid and binding obligation of the Company enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws relating to or affecting the enforcement of creditors’ rights generally and by general equitable principles.

(c) **No Violation; Consents and Approvals.** The execution and delivery by the Company of this Agreement does not, and the consummation by the Company of any of the transactions contemplated hereby and compliance by the Company with the terms, conditions and provisions hereof (including the offer and sale of the Securities by the Company) will not conflict with, violate, result (with the giving of notice or passage of time or both) in a breach of the terms, conditions or provisions of, or constitute a default, an event of default or an event creating rights of acceleration, termination or cancellation or a loss of rights under, or result in the creation or imposition of any Encumbrance upon any of the assets or properties of the Company under (A) the certificate of incorporation or certificate of formation or the by-laws, each as applicable, of the Company, (B) any note, instrument, agreement, contract, mortgage, lease, license, franchise, guarantee, permit or other authorization, right, restriction or obligation to which the Company is a party or any of their respective assets or properties is subject or by which the Company is bound, (C) any Court Order to which the Company is a party or any of their respective assets or properties is subject or by which the Company is bound, or (D) any Requirements of Law applicable to the Company or any of their respective assets or properties.

(d) Capitalization. The Securities will be duly authorized, and when issued in accordance with this Agreement, (i) will be validly issued, fully paid and non-assessable and will be free and clear of any Encumbrances (other than, with respect to the Investor, any Encumbrances created by or through the Investor and restrictions on transfer imposed by the Securities Act, and applicable “blue sky” or other similar laws of the Investor’s state of residence (collectively referred to as the “*State Securities Laws*”)) and the Investor will have good title thereto and (ii) will not have been issued in violation of any preemptive or subscription rights and will not result in the anti-dilution provisions of any security of the Company becoming applicable.

(e) Compliance with Laws. Except as may otherwise be described in the SEC Reports, the Company is in compliance with all laws and regulatory requirements to which it is subject, including U.S. sanctions laws and the Foreign Corrupt Practices Act, 15 U.S.C. §78 et seq., as it may be amended from time to time, except for such non-compliance that (A) could not reasonably be expected to have a Material Adverse Effect or (B) occurs as a result of any proceedings or investigations relating to any matter described in the SEC Reports.

(f) Private Offering. No form of general solicitation or general advertising was used by the Company, or to the knowledge of the Company, its authorized representatives, in connection with the offer or sale of the Securities to be issued under this Agreement. Assuming the accuracy of the representations and warranties of the Investor contained in Section 6, the issuance and sale of the Securities pursuant to this Agreement is exempt from the registration requirements of the Securities Act and applicable State Securities Laws, and neither the Company nor, to the knowledge of the Company, any authorized representative acting on its behalf has taken or will take any action hereafter that would cause the loss of such exemption. The Company agrees that neither it, nor, anyone authorized to act on its behalf, shall offer to sell the Securities to be issued under this Agreement or any other securities of the Company so as to require the registration of the Securities being offered hereby pursuant to the provisions of the Securities Act or any State Securities Laws, unless the offer and sale of the Securities to be issued under this Agreement or such other securities is so registered. Neither the Company nor to its knowledge any Affiliate of the Company, directly or indirectly through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of any security that is or will be integrated with the sale of the Securities in a manner that would require registration of the Securities under the Securities Act.

(g) No Restrictions on Common Stock. Except as described in the SEC Reports, (i) No Person has the right, contractual or otherwise, to cause the Company to issue or sell to it any shares of Common Stock or shares of any other capital stock or other equity interests of the Company and (ii) no Person has any purchase option, call option, preemptive rights, resale rights, subscription rights, rights of first refusal or other rights to purchase any shares of Common Stock or shares of any other capital stock of or other equity interests in the Company.

(h) Investment Company; Passive Foreign Investment Company. The Company is not and, after giving effect to the offer and sale of the Securities will not be an “investment company,” required to register under the Investment Company Act of 1940, as amended. The Company does not believe that it is a “passive foreign investment company” as such term is defined in the Internal Revenue Code of 1986, as amended from time to time, and the regulations promulgated thereunder (the “*Code*”).

(i) Compliance with SEC Filings.

(i) The Company has filed all SEC Reports required to be filed by it with the U.S. Securities and Exchange Commission (the “*SEC*”) for the twelve months preceding the date hereof. As of their respective dates or, if amended, as of the date of such amendment, the SEC Reports complied in all material respects with the requirements of the Securities Act, Exchange Act and the Sarbanes-Oxley Act of 2002 and the applicable rules and regulations promulgated thereunder, and none of the SEC Reports included any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act.

(ii) The audited consolidated financial statements and unaudited consolidated financial statements (including all related notes and schedules) of the Company included in the SEC Reports complied as to form in all material respects with the rules and regulations of the SEC then in effect, fairly present in all material respects the consolidated financial position of the Company and its consolidated subsidiaries, as of the respective dates thereof, and the consolidated results of their operations and their consolidated cash flows for the respective periods then ended (subject, in the case of the unaudited statements, to normal recurring year-end audit adjustments that were not or are not expected to be, individually or in the aggregate, materially adverse to the Company), and were prepared in accordance with U.S. generally accepted accounting principles (“*GAAP*”) applied on a consistent basis during the periods involved, except as otherwise disclosed in the Company SEC Documents.

(j) **Registration and Listing of Common Stock.** The class of Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act. The Common Stock is listed on the NYSE American, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the NYSE American. As of the date of this Agreement, except as disclosed in the SEC Reports, the Company has not received any notification that, and has no knowledge that, the SEC or the NYSE American is contemplating terminating such registration or listing.

6. **Representations and Warranties of the Investor.** As an inducement to the Company to enter into this Agreement and to consummate the transactions contemplated hereby, the Investor represents and warrants, as of the date hereof and as of each Closing Date, as follows:

(a) **Authorization.** The Investor has full power and authority to execute and deliver this Agreement and to perform its obligations hereunder in accordance with the terms hereof. This Agreement has been, and at or prior to each respective Closing will have been, duly executed and delivered by the Investor, and constitutes the legal, valid and binding obligation of the Investor, enforceable against the Investor in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws relating to or affecting the enforcement of creditors' rights generally and by general equitable principles.

(b) **No Consents Required.** No approval, authorization, consent or order of or filing with any federal, state, local or foreign government or regulatory commission, board, body, authority or agency, or of or with any self-regulatory organization, or other non-governmental regulatory authority (including any national securities exchange), is required in connection with the execution, delivery and performance of this Agreement by the Investor or the consummation by the Investor of the transactions contemplated hereby, except for such approvals, authorizations, consents, orders or filings that have been obtained or made and are in full force and effect.

(c) **No Violation.** The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby will not conflict with, result in any breach or violation of or constitute a default under (or constitute any event which with notice, lapse of time or both would result in any breach or violation of or constitute a default under or give the holder of any indebtedness (or a Person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under) (or result in the termination of, or in the creation or imposition of a lien, charge or Encumbrance on any property or assets of the Investor pursuant to) (i) the organizational or other governing documents of the Investor, (ii) any indenture, mortgage, deed of trust, bank loan or credit agreement or other evidence of indebtedness, or any license, lease, contract or other agreement or instrument to which the Investor is a party or by which the Investor or any of its properties may be bound or affected, (iii) any federal, state, local or foreign law, regulation or rule, (iv) any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including any national securities exchange) or (v) any Court Order applicable to the Investor or any of its properties, except in the case of the foregoing clauses (ii), (iii), (iv) and (v) as would not individually or in the aggregate, materially and adversely affect the Investor's ability to perform its obligations under this Agreement or consummate the transactions contemplated herein on a timely basis.

(d) **Financial Capability.** The Investor has available funds necessary to consummate each Closing on the terms and conditions contemplated by this Agreement.

(e) **Accredited Investor and Qualified Institutional Buyer.**

(i) The Investor is acquiring the Securities to be issued under this Agreement to the Investor for its own account, not as nominee or agent, with the present intention of holding such securities for purposes of investment, and not with the view to the public resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the U.S. federal securities laws or any applicable State Securities Laws. The Investor is purchasing and holding any purchased Securities for its own account and is not party to any co-investment, joint venture, partnership or other understandings or arrangements with any other party relating to the Securities or any other transactions contemplated hereunder.

(ii) The Investor is an "accredited investor" as such term is defined in Rule 501(a) of Regulation D under the Securities Act or a "qualified institutional buyer" within the meaning of Rule 144A under the Securities Act and a "qualified purchaser" as defined in Section 2(a)(51)(A) of the Investment Company Act of 1940, as amended.

(iii) The Investor acknowledges that it has completed the Investor Questionnaire contained in Appendix B and that the information contained therein is complete and accurate as of the date thereof and is hereby affirmed as of each Closing Date. Any information that has been furnished or that will be furnished by the Investor to evidence its status as an accredited investor is accurate and complete, and does not contain any misrepresentation or material omission.

(iv) The Investor has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Company, and has so evaluated the merits and risks of such investment, and understands that it may be required to bear the risks thereof. The Investor has previously invested in securities similar to the Securities and fully understands the limitations on transfer and restrictions on sales of the Securities. The Investor represents that it is able to bear the economic risk of its investment in the Securities and is able to afford the complete loss of any such investment.

(v) The Investor has conducted its own independent evaluation, made its own analysis and consulted with advisors as it has deemed necessary, prudent, or advisable in order for the Investor to make its own determination and decision to enter into the transactions contemplated by this Agreement and to execute and deliver this Agreement.

(vi) The Investor has reviewed the SEC Reports and is familiar with the business and financial condition and operations of the Company. The Investor has had an opportunity to discuss the terms and conditions of the offering of the Securities with the Company's management to enable it to evaluate the transactions contemplated by this Agreement and to make an informed investment decision concerning the Securities, and the Investor has had the opportunity to obtain and review information reasonably requested by the Investor.

(vii) The Investor is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or, to the Investor's knowledge, any other general solicitation or general advertisement. Neither the Investor nor its Affiliates or any person acting on its or any of their behalf has engaged, or will engage, in any form of general solicitation or general advertising (within the meaning of Rule 502(c) under the Securities Act) in connection with the offering of the Securities.

(viii) The Investor has sufficient cash on hand or other immediately available funds to pay the Aggregate Purchase Prices and otherwise satisfy its obligations in connection with this Agreement and the transactions contemplated hereby.

(ix) The Investor is not subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) through (viii) under the Securities Act, except for Disqualification Events covered by Rule 506(d)(2)(ii) or (iii) under the Securities Act and disclosed in writing in reasonable detail to the Company.

(f) No Broker's Fees. No brokerage or finder's fees or commissions are or will be payable by the Investor or any of its Affiliates or subsidiaries (if applicable) to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the issuance of the Securities, and the Investor has not taken any action that could cause the Company to be liable for any such fees or commissions. The Investor is not a broker-dealer registered with the SEC under the Exchange Act or an entity engaged in a business that would require it to be so registered.

(g) Advisors. The Investor acknowledges that, prior to entering into this Agreement, it was advised by Persons deemed appropriate by the Investor concerning this Agreement and the transactions contemplated hereunder and conducted its own due diligence investigation and made its own investment decision with respect to this Agreement, the transactions contemplated hereunder and the purchase of the Securities.

(h) Arm's Length Transaction. The Investor is acting solely in the capacity of an arm's length contractual counterparty to the Company with respect to the transactions contemplated hereby. Additionally, without derogating from or limiting the representations and warranties of the Company, the Investor (A) is not relying on the Company for any legal, tax, investment, accounting or regulatory advice; (B) has consulted with its own advisors concerning such matters; and (C) shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby.

(i) No Further Reliance. The Investor acknowledges that it is not relying upon any representation or warranty made by the Company that is not set forth in this Agreement or in the Company's public filings. The Investor confirms that the Company has not (i) given any guarantee or representation as to the potential success, return, effect or benefit (either legal, regulatory, tax, financial, accounting or otherwise) of an investment in the Securities or (ii) made any representation to the Investor regarding the legality of an investment in the Securities under applicable legal investment or similar laws or regulations, except as set forth herein. The Investor confirms that (i) it has conducted a review and analysis of the business, assets, condition, operations and prospects of the Company, and the terms of the Securities, and has access to such financial and other information regarding the Company, in each case that the Investor considers sufficient for purposes of the purchase of the Securities; (ii) at a reasonable time prior to its purchase of the Securities, it had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Securities and to obtain additional information necessary to verify any information furnished to the Investor or to which the Investor had access; and (iii) it has not received any offering memorandum or offering document in connection with the offering of the Securities.

(j) Private Placement. The Investor understands and acknowledges that:

(i) The Securities that it is acquiring under this Agreement are being sold pursuant to an exemption from registration under the Securities Act. The Company may require additional information from the Investor in respect of matters under such exemption from registration under the Securities Act, and the Investor shall provide such reasonably requested information to the Company on a timely basis so that the Company may comply with the requirements thereunder.

(ii) Its representations and warranties contained herein (including the accompanying Investor Questionnaire) are being relied upon by the Company as a basis for such exemption under the Securities Act and under the State Securities Laws. The Investor further understands that, unless it notifies the Company in writing to the contrary at or before each Closing Date, each of the Investor's representations and warranties contained in this Agreement will be deemed to have been automatically (and without any further action of the Investor) reaffirmed and confirmed as of each Closing Date, taking into account all information received by the Investor. The Investor agrees to hold the Company and its directors, officers, employees, affiliates, controlling persons, and agents harmless, and to indemnify them against any and all liabilities, costs, and expenses incurred by them as a result of (i) any misrepresentation made by the Investor contained in this Agreement or the accompanying Investor Questionnaire; (ii) any sale or distribution by the Investor in violation of the Securities Act or any applicable state securities or "blue sky" laws; or (iii) any untrue statement of a material fact made by the Investor and contained herein.

(iii) No U.S. state or federal agency or any other securities regulator of any state or country has passed upon or made any recommendation or endorsements of the merits or risks of an investment in the Securities or made any finding or determination as to the fairness of the terms of the offering of the Securities or any recommendation or endorsement thereof.

(iv) The Securities are "restricted securities" under applicable federal securities laws and that the Securities Act and the rules of the U.S. Securities and Exchange Commission (the "**SEC**") provide in substance that the Investor may dispose of the Securities only pursuant to an effective registration statement under the Securities Act or an exemption therefrom, and the Investor understands that, except as may be described in the SEC Reports, the Company has no obligation or intention to register any of the Securities. The Investor understands that under the SEC's rules, the Investor may dispose of the Securities principally only in "private placements" or other transactions that are exempt from registration under the Securities Act, in which event the transferee may acquire "restricted securities" subject to the same limitations as in the hands of the Investor. Consequently, the Investor understands that the Investor must bear the economic risks of the investment in the Securities for an indefinite period of time. The Investor understands that the Company is under no obligation to register any of the Securities under the Securities Act or any state securities or "blue sky" laws. The Investor will not sell, assign, pledge, give, transfer or otherwise dispose of the Securities or any interest therein, or make any offer or attempt to do any of the foregoing, except pursuant to a registration of the Securities under the Securities Act and all applicable State Securities Laws, or in a transaction which is exempt from the registration provisions of the Securities Act and all applicable State Securities Laws. The Investor understands that that the recordation of the Securities in book-entry form will include a legend substantially in the form indicated in Section 7 (which the Investor has read and understands), and that the Company and its Affiliates shall not be required to give effect to any purported transfer of such Securities except upon compliance with the foregoing restrictions.

(k) No ERISA Plans. Either (a) the Investor is not purchasing or holding Securities (or any interest in Securities) with the assets of (i) an employee benefit plan that is subject to Title I of ERISA, (ii) a plan, individual retirement account or other arrangement that is subject to Section 4975 of the Code, (iii) an entity whose underlying assets are considered to include "plan assets" of any of the foregoing by reason of such plan's, account's or arrangement's investment in such entity, or (iv) a governmental, church, non-U.S. or other plan that is subject to any similar laws; or (b) the purchase and holding of such Securities by the Investor, throughout the period that it holds such Securities, and the disposition of such Securities or an interest therein will not constitute (x) a non-exempt prohibited transaction under Section 406 of ERISA or Section 4975 of the Code, (y) a breach of fiduciary duty under ERISA or (z) a similar violation under any applicable similar laws.

7. Additional Agreements.

(a) Short Selling Acknowledgement and Agreement. The Investor understands and acknowledges that the SEC currently takes the position that coverage of Short Sales of securities "against the box" prior to the effective date of a registration statement is a violation of Section 5 of the Securities Act and of Securities Act Compliance Disclosure Interpretation 239.10. The Investor agrees that it will abide by such interpretation and will not engage in any Short Sales that result in the disposition of the Securities acquired hereunder by the Investor until such time as a resale registration statement is declared or deemed effective by the SEC or such Securities are no longer subject to any restrictions on resale. "**Short Sales**" means all "short sales" as defined in Rule 200 promulgated under Regulation SHO under the Exchange Act, whether or not against the box, and forward sale contracts, options, puts, calls, short sales, "put equivalent positions" (as defined in Rule 16a-1(h) under the Exchange Act) and similar arrangements, and sales and other transactions through non-U.S. broker dealers or foreign regulated brokers.

(b) Legend. The book-entry account maintained by the transfer agent evidencing ownership of the Securities sold pursuant to this Agreement will bear the following restrictive legend in substantially the following form:

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), OR THE SECURITIES LAWS OF ANY STATE. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT (1) OUTSIDE THE UNITED STATES IN AN OFFSHORE TRANSACTION IN COMPLIANCE WITH RULE 903 OR RULE 904 UNDER THE SECURITIES ACT, PURSUANT TO THE EXEMPTION FROM REGISTRATION PROVIDED BY RULE 144 UNDER THE SECURITIES ACT (IF AVAILABLE), OR ANOTHER EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT (AND BASED UPON AN OPINION OF COUNSEL IF THE ISSUER SO REQUESTS), OR (2) PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT.”

(c) Lock-Up. Investor hereby agrees not to sell, make any short sale of, loan, hypothecate, pledge, grant any option for the purchase of or otherwise dispose of any Securities purchased at each respective Closing until the expiration of more than 180 days following each Closing Date.

(d) Blue Sky. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the offer and sale of the Securities to the Investor pursuant to this Agreement under applicable State Securities Laws (or to obtain an exemption from such qualification), and shall provide evidence of any such action so taken to the Investor. The Company shall timely make all filings and reports relating to the offer and sale of the Securities issued hereunder required under applicable State Securities Laws. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section 7(d).

(e) Rule 144 Reporting. For so long as the Investor holds Securities that are not freely transferable without restriction under the Securities Act (including the current public information requirement under Rule 144 of the Securities Act), the Company shall (i) make and keep public information available, as those terms are understood and defined in Rule 144 of Securities Act; and (ii) file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act.

8. **Conditions to Obligations of the Company**. The obligation of the Company to sell and issue the Securities being sold and issued by it to the Investor on each Closing Date is subject to the fulfillment on or before such Closing Date of the following conditions, any of which may be waived (in whole or in part) by the Company in its sole discretion:

(a) No Injunction. As of each Closing Date, no Governmental Body nor any other Person shall have issued an order, injunction, judgment, decree, ruling or assessment which shall then be in effect restraining or prohibiting the completion of the transactions contemplated by this Agreement, nor to the Company’s knowledge, shall any such order, injunction, judgment, decree, ruling or assessment be threatened or pending.

(b) Purchase Price Paid. The Investor shall have paid the applicable Aggregate Purchase Price to the Company, pursuant to the requirements of this Agreement.

(c) Covenants and Agreements. The Investor shall have performed and complied with the covenants and agreements required to be performed or complied with by the Investor hereunder on or prior to each Closing Date.

(d) Representations and Warranties. The representations and the warranties of the Investor contained in this Agreement shall be true and correct in all material respects as of each Closing Date, with the same effect as though such representations and warranties had been made on and as of such date.

9. **Conditions to Obligations of the Investor**. The obligation of the Investor to pay the Company the applicable Aggregate Purchase Price in respect of the Securities to be issued under this Agreement to the Investor is subject to the fulfillment to the reasonable satisfaction of, or, to the extent permitted by law, waiver by, the Investor prior to each Closing Date, as the case may be, each of the following conditions:

(a) Covenants and Agreements. The Company shall have performed and complied in all material respects with the covenants and agreements required to be performed or complied with by it hereunder on or prior to each Closing Date, as applicable.

(b) Representations and Warranties. The representations and the warranties of the Company contained in this Agreement shall be true and correct in all material respects as of each Closing Date, except with respect to provisions including the terms “material,” “Material Adverse Effect” or words of similar import and except with respect to materiality, as reflected under GAAP, and with respect to which such representations and warranties made as of the applicable date, such representations and warranties shall be true and correct only as of such date.

10. **Miscellaneous.**

(a) **Survival of Obligations.** All representations, warranties, covenants, agreements and obligations contained in this Agreement shall survive (i) the acceptance of the Subscriptions by the Company and each Closing and (ii) the death or disability of the Investor.

(b) **Notices.** All notices or other communications required or permitted hereunder shall be in writing and shall be deemed given or delivered (i) when delivered personally, (ii) when delivered by electronic mail (so long as notification of a failure to deliver such electronic mail is not received by the sending party), (iii) if transmitted by electronic mail when confirmation of transmission is received by the sending party, (iv) if sent by registered or certified mail, postage prepaid, return receipt requested, on the third business day after mailing or (v) if sent by reputable overnight courier when received; and shall be addressed to the Investor as set forth on its respective signature pages and if to the Company as follows:

If to the Company: Navidea Biopharmaceuticals, Inc.
4995 Bradenton Avenue
Suite 240
Dublin, Ohio 43017
Attention: Jed A. Latkin, Chief Executive Officer
Email: jlatkin@navidea.com

with a copy to: Thompson Hine LLP
335 Madison Avenue
12th Floor
New York, New York 10017-4611
Attention: Faith L. Charles
Email: Faith.Charles@ThompsonHine.com

If to the Investor: John K. Scott Jr.
5251 DTC Parkway, Suite 285
Greenwood Village, Colorado 80111
Email: jks3@cheqnet.net

With a copy to: Winstead PC
401 Congress Ave.
Suite 2100
Austin, Texas 78701-3619
Attention: James G. Ruiz
Email: jruiz@winstead.com

Any party hereto may, from time to time, change its address, e-mail address or other information for the purpose of notices to that party by giving notice specifying such change to the other parties hereto.

(c) **Execution in Counterparts; Effectiveness.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, and shall become binding when one or more counterparts have been signed by and delivered to each of the parties hereto.

(d) **Amendments.** This Agreement shall not be amended, modified or supplemented except by a written instrument signed by all the parties hereto.

(e) **Expenses.** The Investor shall be responsible for its own costs and expenses in connection herewith, including the fees and expenses, if any, of its advisors and its counsel.

(f) **Waiver.** Any term or provision of this Agreement may be waived, or the time for its performance may be extended, by the party entitled to the benefit thereof. Any such waiver shall be validly and sufficiently authorized for the purposes of this Agreement if, as to any party, it is in writing signed by an authorized representative of such party. The failure or delay of any party to enforce at any time any provision of this Agreement shall not be construed to be a waiver of such provision, nor in any way to affect the validity of this Agreement or any part hereof or the right of any party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach.

(g) **Severability.** Wherever possible, each provision hereof shall be interpreted in such manner as to be effective and valid under applicable law, but in case any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such provision shall be ineffective to the extent, but only to the extent, of such invalidity, illegality or unenforceability without invalidating the remainder of such invalid, illegal or unenforceable provision or provisions or any other provisions hereof, unless such a construction would be unreasonable.

(h) Assignment; Successors and Assigns. Neither this Agreement nor any of the rights and obligations of any party hereunder may be assigned, delegated or otherwise transferred by such party without the prior written consent of each other party; provided, however, that the Investor may assign this Agreement to any Affiliate of the Investor without the consent of the Company. No such assignment, delegation or other transfer shall relieve the assignor of any of its obligations or liabilities hereunder. This Agreement shall be binding upon and shall inure to the benefit of the parties and their respective successors and permitted assigns.

(i) No Third Party Beneficiaries. Nothing in this Agreement, express or implied, is intended or shall be construed to confer upon any third Person, other than the parties and their respective successors and assigns permitted by Section 10(h), any right, remedy or claim under or by reason of this Agreement.

(j) Governing Law. This Agreement shall be governed by and construed in accordance with the substantive laws of the State of New York without regard to its conflict of laws principles.

(k) Submission to Jurisdiction. Each of the parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the non-exclusive jurisdiction of the state district courts of the State of Colorado and of the United States District Court of the District of Colorado, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Agreement, or for recognition or enforcement of any judgment, and each of the parties hereto hereby irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such Colorado State or, to the extent permitted by law, in such Federal court. Each of the parties hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Nothing in this Agreement shall affect any right that the Investor may otherwise have to bring any action or proceeding relating to this Agreement against the Company and its subsidiaries or their respective properties in the courts of any jurisdiction or any right that the Company may otherwise have to bring any action or proceeding relating to this Agreement against the Investor or its properties in the courts of any jurisdiction. Each party hereto irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of venue of any such proceeding brought in such a court referred to in the first sentence of this Section 10(k) and any claim that any such proceeding brought in such a court has been brought in an inconvenient forum.

(l) Waiver of Jury Trial. EACH PARTY HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, TO IT THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

(m) Public Announcements. The Investor shall not make any public announcements or otherwise communicate with the news media with respect to this Agreement or the transactions contemplated hereby without the prior written consent of the Company. Notwithstanding the forgoing, the Investor may make or cause to be made any press release or similar public announcement or communication as may be required to comply with (i) the requirements of applicable law, including the Exchange Act or (ii) its disclosure obligations or practices with respect to its investors; *provided* that prior to making any such disclosure under this clause (ii), the Investor shall provide a copy of such proposed disclosure to the Company and shall only publicly make such disclosure with the consent of the Company, which consent shall not be unreasonably withheld or delayed, if the Company has not previously made a public announcement of the transactions contemplated hereby.

(n) Entire Agreement. This Agreement and the Appendices, and the documents delivered pursuant hereto and thereto constitute the entire agreement and understanding among the parties with respect to the subject matter contained herein or therein, and supersede any and all prior agreements, negotiations, discussions, understandings, term sheets or letters of intent between or among any of the parties with respect to such subject matter.

(o) Interpretation.

In this Agreement, unless the context clearly indicates otherwise:

- (i) words used in the singular include the plural and words in the plural include the singular;
 - (ii) reference to any gender includes the other gender;
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(iii) the word “including” (and with correlative meaning “include”) means “including but not limited to” or “including without limitation”;

(iv) reference to any Section or Appendix means such Section of, or such Appendix to, this Agreement, as the case may be, and reference in any Section or definition to any clause means such clause of such Section or definition;

(v) the words “herein,” “hereunder,” “hereof,” “hereto” and words of similar import shall be deemed references to this Agreement as a whole and not to any particular Section or other provision hereof;

(vi) reference to any agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof and by this Agreement;

(vii) reference to any law (including statutes and ordinances) means such law (including all rules and regulations promulgated thereunder) as amended, modified, codified or reenacted, in whole or in part, and in effect at the time of determining compliance or applicability;

(viii) relative to the determination of any period of time, “from” means “from and including,” “to” means “to but excluding” and “through” means “through and including”; and

(ix) the titles and headings of Sections contained in this Agreement have been inserted for convenience of reference only and shall not be deemed to be a part of or to affect the meaning or interpretation of this Agreement.

(p) This Agreement was negotiated by the parties with the benefit of legal representation, and no rule of construction or interpretation otherwise requiring this Agreement to be construed or interpreted against any party shall apply to any construction or interpretation hereof. Subject to Section 10(g), this Agreement shall be interpreted and construed to the maximum extent possible so as to uphold the enforceability of each of the terms and provisions hereof.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the undersigned has executed this Agreement this 22ND DAY OF MARCH, 2019.

INVESTOR:

/s/ John K. Scott Jr.
JOHN K. SCOTT JR.

[Signature Page to Stock Purchase Agreement]

IN WITNESS WHEREOF, the undersigned has executed this Agreement this 22ND OF MARCH, 2019.

NAVIDEA BIOPHARMACEUTICALS, INC.

By: /s/ Jed A. Latkin

Name: Jed A. Latkin

Title: Chief Executive Officer, Chief Financial Officer and Chief Operating Officer

[Signature Page to Stock Purchase Agreement]

INVESTOR QUESTIONNAIRE

Name of Investor: JOHN K. SCOTT JR.

State or jurisdiction of residence: _____

With respect to a potential investment in Navidea Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), the undersigned represents and warrants that he qualifies as an "**accredited investor**" as that term is defined in Rule 501(a) of Regulation D or a non-"**U.S. Person**" as that term is defined in Rule 902(k) promulgated under the Securities Act of 1933, as amended (the "**Act**"), because (please check the box that applies):

- He/she is a natural person whose individual net worth, or joint net worth with his/her spouse, at the time of his/her purchase of securities of the Company, exceeds \$1,000,000, excluding the value of his/her primary residence; or
- He/she is a natural person who had an individual income in excess of \$200,000 in each of the two most recent years or had a joint income with his/her spouse in excess of \$300,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year; or
- He/she is a director, executive officer or general partner of the Company or a director, executive officer or general partner of a general partner of the Company; or
- It is an organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, a corporation, Massachusetts or similar business trust, or partnership that was not formed for the specific purpose of acquiring the securities of the Company being offered in this offering, with total assets in excess of \$5,000,000; or
- It is a "private business development company" as defined in Section 202(a)(22) of the Investment Advisers Act of 1940; or
- It is a "bank" as defined in Section 3(a)(2) of the Act; or
- It is a "savings and loan association" or other institution as defined in Section 3(a)(5)(A) of the Act, whether acting in its individual or fiduciary capacity; or
- It is a broker or dealer registered pursuant to Section 15 of the Securities Exchange Act of 1934, as amended; or
- It is an "insurance company" as defined in Section 2(a)(13) of the Act; or
- It is an investment company registered under the Investment Company Act of 1940; or
- It is a "business development company" as defined in Section 2(a)(48) of the Investment Company Act of 1940; or
- It is a "Small Business Investment Company" licensed by the U.S. Small Business Administration under either Section 301(c) or (d) of the Small Business Investment Act of 1958; or
- It is a plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of \$5,000,000; or
- It is an employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974 if the investment decision is made by a plan fiduciary, as defined in Section 3(21) of such Act, which is one of the following:
- A bank;
 - A savings and loan association;
 - An insurance company; or
 - A registered investment adviser; or
- It is an employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974 with total assets in excess of \$5,000,000; or
- It is an employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974 that is a self-directed plan with investment decisions made solely by persons that are accredited investors; or
- It is a trust with total assets in excess of \$5,000,000, not formed for the specific purpose of acquiring the securities offered by the Company in this offering, whose purchase is directed by a sophisticated person as described in Rule 506(b)(2)(ii); or
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- It is an entity in which all of the equity owners are accredited investors.
- It is not (i) a natural person resident in the United States; (ii) a partnership or corporation organized or incorporated under the laws of the United States; (iii) an estate of which any executor or administrator is a U.S. person; (iv) a trust of which any trustee is a U.S. person; (v) an agency or branch of a foreign entity located in the United States; (vi) a non-discretionary account or similar account (other than an estate or trust) held by a dealer or other fiduciary for the benefit or account of a U.S. person; (vii) a discretionary account or similar account (other than an estate or trust) held by a dealer or other fiduciary organized, incorporated, or (if an individual) resident in the United States; or (viii) a partnership or corporation organized or incorporated under the laws of any foreign jurisdiction; but not formed by a U.S. person principally for the purpose of investing in securities not registered under the Act, unless it is organized or incorporated, and owned, by accredited investors who are not natural persons, estates or trusts.
- It is a discretionary account or similar account (other than an estate or trust) held for the benefit or account of a non-U.S. person by a dealer or other professional fiduciary organized, incorporated, or (if an individual) resident in the United States.
- It is an estate of which any professional fiduciary acting as executor or administrator is a U.S. person but: (A) an executor or administrator of the estate who is not a U.S. person has sole or shared investment discretion with respect to the assets of the estate; and (B) the estate is governed by foreign law.
- It is a trust of which any professional fiduciary acting as trustee is a U.S. person, but a trustee who is not a U.S. person has sole or shared investment discretion with respect to the trust assets, and no beneficiary of the trust (and no settlor if the trust is revocable) is a U.S. person.
- It is an employee benefit plan established and administered in accordance with the law of a country other than the United States and customary practices and documentation of such country.
- It is an agency or branch of a U.S. person located outside the United States but (A) the agency or branch operates for valid business reasons; and (B) The agency or branch is engaged in the business of insurance or banking and is subject to substantive insurance or banking regulation, respectively, in the jurisdiction where located.

Date: _____, 2019

INVESTOR:

JOHN K. SCOTT JR.

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

I, Jed A. Latkin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Navidea Biopharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 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)

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

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

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

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

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

May 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)