
**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, 2017**

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

For the transition period from to _____ 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.)

5600 Blazer Parkway, Suite 200, Dublin, Ohio

(Address of principal executive offices)

43017-7550

(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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
Non-accelerated filer
Emerging Growth Company

Accelerated filer
Smaller reporting company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12-b-2 of the Act.) Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 161,898,338 shares of common stock, par value \$.001 per share (as of the close of business on May 1, 2017).

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, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash	\$ 13,440,618	\$ 1,539,325
Restricted cash	—	5,001,253
Accounts and other receivables	7,185,814	203,016
Inventory, net	748	96,208
Prepaid expenses and other	1,071,815	842,220
Assets associated with discontinued operations, current	—	3,144,247
Total current assets	<u>21,698,995</u>	<u>10,826,269</u>
Property and equipment	3,217,061	3,232,372
Less accumulated depreciation and amortization	2,118,026	2,051,787
	<u>1,099,035</u>	<u>1,180,585</u>
Patents, trademarks and license agreements	480,404	146,685
Guaranteed earnout receivable	9,437,599	—
Other assets	209,554	202,882
Assets associated with discontinued operations	—	105,255
Total assets	<u>\$ 32,925,587</u>	<u>\$ 12,461,676</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 3,133,752	\$ 5,165,385
Accrued liabilities and other	1,170,315	7,857,856
Deferred revenue, current	15,037	15,037
Notes payable, current	2,103,000	51,957,913
Liabilities associated with discontinued operations, current	3,554,320	4,865,597
Total current liabilities	<u>9,976,424</u>	<u>69,861,788</u>
Notes payable	—	9,641,179
Other liabilities	583,849	624,922
Total liabilities	<u>10,560,273</u>	<u>80,127,889</u>
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock; \$.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock; \$.001 par value; 300,000,000 shares authorized; 161,898,338 and 155,762,729 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	161,898	155,763
Additional paid-in capital	330,808,515	326,564,148
Accumulated deficit	(309,273,807)	(394,855,034)
Total Navidea stockholders' equity (deficit)	<u>21,696,606</u>	<u>(68,135,123)</u>
Noncontrolling interest	668,708	468,910
Total stockholders' equity (deficit)	<u>22,365,314</u>	<u>(67,666,213)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 32,925,587</u>	<u>\$ 12,461,676</u>

See accompanying notes to consolidated financial statements.

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

	Three Months Ended	
	March 31,	
	2017	2016
Revenue:		
Tc 99m tilmanocept sales revenue	\$ —	\$ 8,800
Tc 99m tilmanocept license revenue	—	254,050
Grant and other revenue	580,030	685,635
Total revenue	<u>580,030</u>	<u>948,485</u>
Cost of goods sold	—	1,489
Gross profit	<u>580,030</u>	<u>946,996</u>
Operating expenses:		
Research and development	705,274	2,072,271
Selling, general and administrative	3,022,434	2,633,126
Total operating expenses	<u>3,727,708</u>	<u>4,705,397</u>
Loss from operations	<u>(3,147,678)</u>	<u>(3,758,401)</u>
Other (expense) income:		
Interest income, net	24,112	757
Equity in loss of R-NAV, LLC	—	(12,239)
Change in fair value of financial instruments	140,485	1,125,359
Loss on extinguishment of debt	(1,314,102)	—
Other, net	(21,604)	(37,292)
Total other (expense) income, net	<u>(1,171,109)</u>	<u>1,076,585</u>
Loss before income taxes	<u>(4,318,787)</u>	<u>(2,681,816)</u>
Benefit from income taxes	1,454,172	—
Loss from continuing operations	<u>(2,864,615)</u>	<u>(2,681,816)</u>
Discontinued operations, net of tax effect:		
Loss from discontinued operations	(255,861)	(1,004,433)
Gain on sale	88,701,501	—
Net income (loss)	<u>85,581,025</u>	<u>(3,686,249)</u>
Less loss attributable to noncontrolling interest	(202)	(241)
Net income (loss) attributable to common stockholders	<u>\$ 85,581,227</u>	<u>\$ (3,686,008)</u>
Income (loss) per common share (basic):		
Continuing operations	\$ (0.02)	\$ (0.02)
Discontinued operations	\$ 0.55	\$ —
Attributable to common stockholders	\$ 0.53	\$ (0.02)
Weighted average shares outstanding (basic)	160,376,476	155,308,094
Income (loss) per common share (diluted):		
Continuing operations	\$ (0.02)	\$ (0.02)
Discontinued operations	\$ 0.54	\$ —
Attributable to common stockholders	\$ 0.52	\$ (0.02)
Weighted average shares outstanding (diluted)	164,871,955	155,308,094

See accompanying notes to consolidated financial statements.

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

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Non-</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u>	<u>Deficit</u>	<u>controlling</u>	<u>Stockholders'</u>
					<u>Capital</u>		<u>Interest</u>	<u>Equity</u>
								<u>(Deficit)</u>
Balance, January 1, 2017	—	\$ —	155,762,729	\$ 155,763	\$26,564,148	\$394,855,034	\$ 468,910	\$67,666,213
Issued stock in payment of Board retainers	—	—	16,406	16	10,484	—	—	10,500
Issued stock in payment of employee bonuses	—	—	707,353	707	367,105	—	—	367,812
Issued stock upon exercise of warrants	—	—	5,411,850	5,412	48,707	—	—	54,119
Issued warrants in connection with Asset Sale	—	—	—	—	3,337,187	—	—	3,337,187
Issued warrants for extension of license agreement	—	—	—	—	333,719	—	—	333,719
Stock compensation expense	—	—	—	—	147,165	—	—	147,165
Net income	—	—	—	—	—	85,581,227	(202)	85,581,025
Reclassification of funds invested (see Note 8)	—	—	—	—	—	—	200,000	200,000
Balance, March 31, 2017	—	\$ —	161,898,338	\$ 161,898	\$30,808,515	\$309,273,807	\$ 668,708	\$2,365,314

See accompanying notes to consolidated financial statements.

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

	Three Months Ended	
	March 31,	
	2017	2016
Cash flows from operating activities:		
Net income (loss)	\$ 85,581,025	\$ (3,686,249)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	86,535	149,590
Loss on disposal and abandonment of assets	100,270	—
Amortization of debt discount and issuance costs	—	72,875
Compounded interest on long term debt	143,114	824,952
Stock compensation expense	147,165	340,502
Equity in loss of R-NAV, LLC	—	12,239
Change in fair value of financial instruments	(140,485)	(1,125,359)
Issued warrants in connection with Asset Sale	3,337,187	—
Value of stock issued to directors	10,500	20,640
Value of stock issued to employees	367,812	—
Other	65	(12,239)
Changes in operating assets and liabilities:		
Accounts and other receivables	(14,821,403)	903,147
Inventory	1,470,078	(246,030)
Prepaid expenses and other assets	(65,632)	193,795
Accounts payable	(3,837,463)	1,133,840
Accrued and other liabilities	(3,719,024)	4,418
Deferred revenue	(2,315,037)	(265,758)
Net cash provided by (used in) operating activities	<u>66,344,707</u>	<u>(1,679,637)</u>
Cash flows from investing activities:		
Purchases of equipment	—	(1,847)
Net cash used in investing activities	<u>—</u>	<u>(1,847)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	54,119	—
Principal payments on notes payable	(59,498,721)	—
Restricted cash held for payment against debt	5,001,188	—
Payments under capital leases	—	(693)
Net cash used in financing activities	<u>(54,443,414)</u>	<u>(693)</u>
Net increase (decrease) in cash	11,901,293	(1,682,177)
Cash, beginning of period	1,539,325	7,166,260
Cash, end of period	<u>\$ 13,440,618</u>	<u>\$ 5,484,083</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, 2017 and for the three-month periods ended March 31, 2017 and 2016 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 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, 2017 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, 2016, 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 subsidiaries, Navidea Biopharmaceuticals Limited and CardioSonix Ltd, as well as those of our majority-owned subsidiary, Macrophage Therapeutics, Inc. (“MT”). All significant inter-company accounts were eliminated in consolidation. Prior to termination of Navidea’s joint venture with R-NAV, LLC (“R-NAV”), Navidea’s investment in R-NAV was being accounted for using the equity method of accounting and was therefore not consolidated.

On March 3, 2017, pursuant to an Asset Purchase Agreement dated November 23, 2016, (the “Purchase Agreement”), the Company completed its previously announced 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 (the “Business”), including the Company’s radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration (“FDA”) and similar indications approved by the FDA in the future (the “Product”), in Canada, Mexico and the United States (the “Territory”) (giving effect to the License-Back described below and excluding certain assets specifically retained by the Company) (the “Asset Sale”). Such assets sold in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all right, title and interest in and to the Product, as specified in the Purchase Agreement (the “Acquired Assets”).

Upon closing of the Asset Sale, the Supply and Distribution Agreement, dated November 15, 2007 (as amended, the “Supply and Distribution Agreement”), between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect (other than any indemnification, payment, notification or data sharing obligations which survive the termination).

Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the Business as a discontinued operation. Cash flows associated with the operation of the Business have been combined with operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows. See Note 3.

- b. **Financial Instruments and Fair Value:** In accordance with current accounting standards, the fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value, giving the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. In determining the appropriate levels, we perform a detailed analysis of the assets and liabilities whose fair value is measured on a recurring basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3. See Note 4.

The following methods and assumptions were used to estimate the fair value of each class of financial instruments:

- (1) Cash, restricted cash, accounts and other receivables, accounts payable, and accrued liabilities: 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, 2017 and December 31, 2016 primarily consists of the face amount of the notes less unamortized discounts. At March 31, 2017 and December 31, 2016, certain notes payable were also required to be recorded at fair value. The estimated fair value of our debt was calculated using a discounted cash flow analysis as well as a Monte Carlo simulation. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. Unrealized gains and losses on the fair value of the debt are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations. At March 31, 2017, the fair value of our notes payable is approximately \$2.1 million, equal to the carrying value of \$2.1 million. See Note 10.
- (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, 2017 and December 31, 2016 were included in other liabilities on the consolidated balance sheets. The assumptions used to calculate fair value as of March 31, 2017 and December 31, 2016 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 terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. We received a non-refundable upfront cash payment of \$2.0 million from SpePharm AG upon execution of the SpePharm License Agreement in March 2015. We determined that the license and other non-contingent deliverables did not have stand-alone value because the license could not be deemed to be fully delivered for its intended purpose unless we performed our other obligations, including specified development work. Accordingly, they did not meet the separation criteria, resulting in these deliverables being considered a single unit of account. As a result, revenue relating to the upfront cash payment was deferred and was being recognized on a straight-line basis over the estimated obligation period of two years. However, the remaining deferred revenue of \$417,000 was recognized upon obtaining European approval of a reduced-mass vial in September 2016, several months earlier than originally anticipated.

- d. **Recently Adopted Accounting Standards:** In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Compensation – Stock Compensation (Topic 178): Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for public business entities for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Methods of adoption vary according to each of the amendment provisions. The adoption of ASU 2016-09 on January 1, 2017 did not have a material impact on the Company's financial statements as:

- As of December 31, 2016, \$15.3 million of our U.S. net operating loss carryforwards related to stock-based compensation tax deductions in excess of book compensation expense ("APIC NOLs"), that will be credited to additional paid-in capital when such deductions reduce taxes payable as determined on a "with-and-without" basis. Accordingly, these APIC NOLs will reduce federal taxes payable if realized in future periods. As of December 31, 2016, we have also recorded a full valuation allowance against these APIC NOLs. This resulted in a zero cumulative effect adjustment to accumulated deficit as a result of the adoption of ASU 2016-09.
- Due to the full valuation allowance for the Company's tax provision, these APIC NOLs have never been recorded in additional paid-in-capital. The Company does not anticipate any impact going forward as any amounts to be recorded in the consolidated statements of operations would be fully offset by the valuation allowance, nor would they result in a related classification in cash flows for operating activities.

- The Company will continue to recognize forfeitures through estimates consistent with our past practices as opposed to when they occur.
- The Company already classifies cash paid to taxing authorities arising from the withholding of shares from employees in cash flows from financing activities.

2. Liquidity

Prior to the Asset Sale to Cardinal Health 414 in March 2017, all of our material assets were pledged as collateral for our borrowings under the Term Loan Agreement (the “CRG Loan Agreement”) with CRG. In addition to the security interest in our assets, the CRG Loan Agreement carried covenants that imposed significant requirements on us. An event of default would have entitled CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to CRG under the loan agreement and the related security agreement. During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company’s primary bank accounts and took possession of \$4.1 million that was on deposit.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of the settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million (the “Deposit Amount”) of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents (the “Final Payoff Amount”). The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million (the “Low Payoff Amount”) and no more than \$66 million (the “High Payoff Amount”). In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a \$7 million letter of credit in favor of CRG (at the Company’s cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414’s indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG’s letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case were released to the Company following the closing of the Asset Sale.

In addition, our Loan Agreement with Platinum-Montaur Life Sciences LLC, an affiliate of Platinum Management (NY) LLC, Platinum Partners Value Arbitrage Fund L.P., Platinum Partners Liquid Opportunity Master Fund L.P., Platinum Liquid Opportunity Management (NY) LLC, and Montsant Partners LLC (collectively, “Platinum”) (the “Platinum Loan Agreement”) carries standard non-financial covenants typical for commercial loan agreements that impose significant requirements on us. Our ability to comply with these provisions may be affected by changes in our business condition or results of our operations, or other events beyond our control. The breach of any of these covenants would result in a default under the Platinum Loan Agreement, permitting Platinum to accelerate the maturity of the debt. Such actions by Platinum could adversely affect our operations, results of operations and financial condition, including causing us to curtail our product development activities.

The Platinum Loan Agreement includes a covenant that results in an event of default on the Platinum Loan Agreement upon default on the CRG Loan Agreement. As discussed above, the Company is maintaining its position that CRG’s alleged claims do not constitute events of default under the CRG Loan Agreement and believes it has defenses against such claims. The Company has obtained a waiver from Platinum confirming that we are not in default under the Platinum Loan Agreement as a result of the alleged default on the CRG Loan Agreement and as such, we are currently in compliance with all covenants under the Platinum Loan Agreement.

In connection with the closing of the Asset Sale to Cardinal Health 414, the Company repaid to Platinum Partners Credit Opportunities Master Fund, LP (“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 Life Sciences, LLC (“Platinum-Montaur”), which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by Platinum Partners Value Arbitrage Fund LP (“PPVA”) that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company’s President and Chief Executive Officer, and PPVA.

Based on our projected cash burn for the next twelve months, we believe that substantial doubt about the Company’s financial position and ability to continue as a going concern has been mitigated due to the Company’s efforts achieved, and planned, in reducing salaries and facilities expenses and our considerable discretion over the extent of development project expenditures that are included in the current budget. Although we could still be required to pay up to an additional \$7 million to CRG depending upon the outcome of the Texas litigation, the Company’s management believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Quarterly Report on Form 10-Q.

3. Discontinued Operations

On March 3, 2017, the Company completed the sale to 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, 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 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 additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414’s right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments of \$6.7 million per year for each of the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG. This advance is to be applied to the third year of guaranteed payments.

We recorded a net gain on the sale of the Business of \$88.7 million for the three months ended March 31, 2017, including \$16.5 in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by \$3.3 million in estimated fair value of warrants issued to Cardinal Health 414, \$2.0 million in legal and other fees related to the sale, \$800,000 in net balance sheet dispositions and write-offs, and \$4.6 million in estimated taxes.

As a result of the Asset Sale, we reclassified certain assets and liabilities as assets and liabilities associated with discontinued operations. The following assets and liabilities have been segregated and included in assets associated with discontinued operations or liabilities associated with discontinued operations, as appropriate, in the consolidated balance sheets:

	March 31, 2017	December 31, 2016
Accounts and other receivables	\$ —	\$ 1,598,994
Inventory, net	—	1,374,618
Prepaid expenses	—	170,635
Assets associated with discontinued operations, current	—	3,144,247
Property and equipment, net of accumulated depreciation	—	70,973
Patents and trademarks, net of accumulated amortization	—	34,282
Assets associated with discontinued operations, noncurrent	—	105,255
Total assets associated with discontinued operations	<u>\$ —</u>	<u>\$ 3,249,502</u>
Accounts payable	\$ 152,108	\$ 1,957,938
Accrued liabilities	3,402,212	607,659
Deferred revenue	—	2,300,000
Liabilities associated with discontinued operations, current	<u>\$ 3,554,320</u>	<u>\$ 4,865,597</u>

In addition, we reclassified certain revenues and expenses related to the Business to discontinued operations for all periods presented, including interest expense related to the CRG and Platinum debt obligations as required by current accounting guidance. The following amounts have been segregated from continuing operations and included in discontinued operations in the consolidated statements of operations:

	Three Months Ended March 31,	
	2017	2016
Revenue:		
Lymphoseek sales revenue	\$ 2,917,213	\$ 3,773,880
Grant and other revenue	—	190
Total revenue	<u>2,917,213</u>	<u>3,774,070</u>
Cost of goods sold	<u>364,192</u>	<u>533,440</u>
Gross profit	<u>2,553,021</u>	<u>3,240,630</u>
Operating expenses:		
Research and development	283,533	587,249
Selling, general and administrative	820,203	1,463,534
Total operating expenses	<u>1,103,736</u>	<u>2,050,783</u>
Income from discontinued operations	<u>1,449,285</u>	<u>1,189,847</u>
Interest expense	<u>(1,718,506)</u>	<u>(2,194,280)</u>

Benefit from income taxes	(269,380)	(1,004,433)
Loss from discontinued operations	<u>\$ (255,861)</u>	<u>\$ (1,004,433)</u>

4. Fair Value

The Company has been informed by PPVA that it is the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

Platinum or Dr. Goldberg has the right to convert all or any portion of the unpaid principal or unpaid interest accrued on all draws under the Platinum credit facility, under certain circumstances. The Platinum debt instrument, including the embedded option to convert such debt into common stock, is recorded at fair value on the consolidated balance sheets and deemed to be a derivative instrument as the amount of shares to be issued upon conversion is indeterminable. The estimated fair value of the Platinum notes payable is \$1.9 million and \$9.6 million at March 31, 2017 and December 31, 2016, respectively.

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, 2017 and December 31, 2016, and will continue to be measured on a recurring basis. See Note 1(b)(3).

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

Liabilities Measured at Fair Value on a Recurring Basis as of March 31, 2017

Description	Quoted Prices in			Total
	Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Platinum notes payable	\$ —	\$ —	\$ 1,926,218	\$ 1,926,218
Liability related to MT warrants	—	—	63,000	63,000

Liabilities Measured at Fair Value on a Recurring Basis as of December 31, 2016

Description	Quoted Prices in			Total
	Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Platinum notes payable	\$ —	\$ —	\$ 9,641,179	\$ 9,641,179
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. Each reporting period, the Company provides significant unobservable inputs to the third-party valuation experts based on current internal estimates and forecasts.

The assumptions used in the Monte Carlo simulation as of March 31, 2017 and December 31, 2016 are summarized in the following table:

	March 31, 2017	December 31, 2016
Estimated volatility	110%	76%
Expected term (in years)	0.43	4.75
Debt rate	8.125%	8.125%
Beginning stock price	\$ 0.58	\$ 0.64

- b. **Sensitivity Analysis-Level 3 Measurements:** Changes in the Company's current internal estimates and forecasts are likely to cause material changes in the fair value of certain liabilities. The significant unobservable inputs used in the fair value measurement of the liabilities include the amount and timing of future draws expected to be taken under the Platinum Loan Agreement based on current internal forecasts and management's estimate of the likelihood of actually making those draws as opposed to obtaining other sources of financing. Significant increases (decreases) in any of the significant unobservable inputs would result in a higher (lower) fair value measurement. A change in one of the inputs would not necessarily result in a directionally similar change in the others.

There were no Level 1 or Level 2 liabilities outstanding at any time during the three-month periods ended March 31, 2017 and 2016. There were no transfers in or out of our Level 1 or Level 2 liabilities during the three-month periods ended March 31, 2017 or 2016. Changes in the estimated fair value of our Level 3 liabilities relating to unrealized gains (losses) are recorded as changes in fair value of financial instruments in the consolidated statements of operations. The change in the estimated fair value of our Level 3 liabilities during the three-month periods ended March 31, 2017 and 2016 was decreases of \$140,000 and \$1.1 million, respectively.

5. Stock-Based Compensation

For the three-month periods ended March 31, 2017 and 2016, our total stock-based compensation expense, which includes reversals of expense for certain forfeited or cancelled awards, was approximately \$147,000 and \$341,000, respectively. We have not recorded any income tax benefit related to stock-based compensation in either of the three-month periods ended March 31, 2017 and 2016.

In September 2016, the Board of Directors approved the 2016 Stock Incentive Plan (the "2016 Plan"), authorizing a total of 10 million shares. The 2016 Plan has not yet been approved by Navidea's stockholders. In connection with Dr. Goldberg's appointment as Chief Executive Officer of the Company in September 2016, the Board of Directors awarded options to purchase 5,000,000 shares of our common stock to Dr. Goldberg, subject to stockholder approval of the 2016 Plan. If approved, these stock options will vest 100% when the average closing price of the Company's common stock over a period of five consecutive trading days equals or exceeds \$2.50 per share, and expire on the tenth anniversary of the date of grant.

A summary of the status of our stock options as of March 31, 2017, and changes during the three-month period then ended, is presented below:

	Three Months Ended March 31, 2017			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at beginning of period	3,380,615	\$ 2.00		
Granted	—	—		
Exercised	—	—		
Canceled and Forfeited	(108,150)	1.48		
Expired	—	—		
Outstanding at end of period	<u>3,272,465</u>	<u>\$ 2.01</u>	<u>6.2 years</u>	<u>\$ 10,922</u>
Exercisable at end of period	<u>3,002,405</u>	<u>\$ 2.04</u>	<u>6.1 years</u>	<u>\$ 10,922</u>

A summary of the status of our unvested restricted stock as of March 31, 2017, and changes during the three-month period then ended, is presented below:

	Three Months Ended March 31, 2017	
	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at beginning of period	207,000	\$ 1.17
Granted	—	—
Vested	—	—
Forfeited	—	—
Unvested at end of period	<u>207,000</u>	<u>\$ 1.17</u>

As of March 31, 2017, there was approximately \$101,000 of total unrecognized compensation expense related to unvested stock-based awards, which we expect to recognize over the remaining weighted average vesting term of 1.4 years.

6. Earnings (Loss) Per Share

Basic earnings (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares and, except for periods with a loss from operations, participating securities outstanding during the period. Diluted earnings (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.

The following table sets forth the reconciliation of the weighted average number of common shares outstanding used to compute basic and diluted earnings (loss) per share for the three-month periods ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
	2017	2016
Weighted average shares outstanding, basic	160,376,476	155,308,094
Dilutive shares related to warrants	4,288,479	—
Unvested restricted stock	207,000	—
Weighted average shares outstanding, diluted	<u>164,871,955</u>	<u>155,308,094</u>

Diluted earnings (loss) per common share for the three-month periods ended March 31, 2017 and 2016 excludes the effects of 15.9 million and 15.1 million 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, and upon the conversion of convertible debt and convertible preferred stock.

The Company's unvested stock awards contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid (referred to as "participating securities"). Therefore, the unvested 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, 207,000 and 134,000 shares of unvested restricted stock for the three-month periods ended March 31, 2017 and 2016, respectively, were excluded in determining basic and diluted loss per share from continuing operations because such inclusion would be anti-dilutive.

7. Inventory

All components of inventory are valued at the lower of cost (first-in, first-out) or net realizable value. We adjust inventory to net realizable value if the net realizable value is lower than the carrying cost of the inventory. Net realizable value is determined based on estimated sales activity and margins. We estimate a reserve for obsolete inventory based on management's judgment of probable future commercial use, which is based on an analysis of current inventory levels, estimated future sales and production rates, and estimated shelf lives.

The components of inventory as of March 31, 2017 and December 31, 2016 are as follows:

	March 31, 2017 (unaudited)	December 31, 2016
Materials	\$ —	\$ 94,500
Work-in-process	—	1,708
Finished goods	748	—
Reserves	—	—
Total	\$ 748	\$ 96,208

8. Investment in Macrophage Therapeutics, Inc.

In March 2015, Platinum and Dr. Goldberg (collectively, the "MT Investors") invested \$300,000 and \$200,000, respectively, in MT in exchange for shares of MT's Series A Convertible Preferred Stock ("MT Preferred Stock") and warrants to purchase common shares of MT ("MT Common Stock"). The MT Preferred Stock and warrants are convertible into, and exercisable for, MT Common Stock.

In December 2015 and May 2016, Platinum made additional investments in MT totaling \$200,000. MT was not obligated to provide anything in return, although it was considered likely that the MT Board of Directors would ultimately authorize some form of compensation to Platinum. During the year ended December 31, 2016, the Company recorded the entire additional \$200,000 investment as a current liability pending determination of the form of compensation.

In 2016, MT's Board of Directors authorized modification of the original MT Preferred Stock to a convertible preferred stock with a 10% paid-in-kind ("PIK") coupon retroactive to the time the initial investments were made. The conversion price of the MT Preferred Stock will remain at the \$500 million initial market cap but a full ratchet was added to enable the adjustment of conversion price, warrant number and exercise price based on the valuation of the first institutional investment round. In addition, the MT Board of Directors authorized issuance of additional MT Preferred Stock with the same terms to Platinum as compensation for the additional \$200,000 of investments made in December 2015 and May 2016. Based on the decision to issue equity for the additional \$200,000 of investments made by Platinum, the liability was reclassified to additional paid-in-capital in January 2017. As of the date of filing of this Form 10-Q, final documents related to the above transactions authorized by the MT Board have not been completed.

9. Accounts Payable, Accrued Liabilities and Other

Accounts payable at March 31, 2017 and December 31, 2016 includes an aggregate of \$81,000 and \$116,000, respectively, due to related parties related to director fees and MT scientific advisory board fees. At March 31, 2017, approximately \$990,000 of accounts payable is being disputed by the Company related to unauthorized expenditures by a former executive and related legal fees incurred during the year ended December 31, 2016.

Accrued liabilities and other at March 31, 2017 and December 31, 2016 includes an aggregate of \$362,000 and \$106,000, respectively, due to related parties related to executive bonuses, director fees, deferred salary owed to Dr. Goldberg, and MT scientific advisory board fees.

10. Notes Payable

Platinum

In July 2012, we entered into an agreement with Platinum-Montaur to provide us with a credit facility of up to \$50 million. In connection with the closing of the Asset Sale to Cardinal Health 414, 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, which, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum Note. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

During the three-month periods ended March 31, 2017 and 2016, \$143,000 and \$306,000 of interest was compounded and added to the balance of the Platinum Note, respectively. As of March 31, 2017, the remaining outstanding principal balance of the Platinum Note was approximately \$1.9 million.

The Platinum Note is reflected on the consolidated balance sheets at its estimated fair value, which includes the estimated fair value of the embedded conversion option of \$13,000 and \$153,000 at March 31, 2017 and December 31, 2016, respectively. Changes in the estimated fair value of the Platinum Note were decreases of \$140,000 and \$1.1 million, respectively, and were recorded as non-cash changes in fair value of the conversion option during the three-month periods ended March 31, 2017 and 2016. The estimated fair value of the Platinum Note was \$1.9 million and \$9.6 million as of March 31, 2017 and December 31, 2016, respectively.

Capital Royalty Partners II, L.P.

In May 2015, Navidea and its subsidiary Macrophage Therapeutics, Inc., as guarantor, executed a Term Loan Agreement (the CRG Loan Agreement) with Capital Royalty Partners II L.P. (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 which the Lenders agreed to make a term loan to the Company in the aggregate principal amount of \$50 million (the CRG Term Loan), with an additional \$10 million in loans to be made available upon the satisfaction of certain conditions stated in the CRG Loan Agreement. During the three-month period ended March 31, 2016, \$519,000 of interest was compounded and added to the balance of the CRG Term Loan.

Pursuant to a notice of default letter sent to Navidea by CRG in April 2016, the Company stopped compounding interest in the second quarter of 2016 and began recording accrued interest. As of December 31, 2016, \$5.8 million of accrued interest related to the CRG Term Loan is included in accrued liabilities and other on the consolidated balance sheets. As of December 31, 2016, the outstanding principal balance of the CRG Term Loan was \$51.7 million.

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company's primary bank accounts and took possession of \$4.1 million that was on deposit.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of the settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million and no more than \$66 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a \$7 million letter of credit in favor of CRG as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case were released to the Company following the closing of the Asset Sale.

In December 2016, we prepaid \$348,000 of insurance premiums through the issuance of a note payable to IPFS Corporation (“IPFS”) with an interest rate of 8.99%. The note is payable in eight monthly installments of \$45,000, with the final payment due on July 10, 2017. As of March 31, 2017 and December 31, 2016, the remaining outstanding principal balance of the IPFS note payable is approximately \$177,000 and \$306,000, respectively, and is included in notes payable, current in the consolidated balance sheets.

Summary

During the three-month periods ended March 31, 2017 and 2016, we recorded interest expense of \$1.7 million and \$2.2 million, respectively, related to our notes payable. Of these amounts, \$0 and \$73,000, respectively, related to amortization of the debt discounts related to our notes payable. An additional \$143,000 and \$825,000 of total interest expense was compounded and added to the balance of our notes payable during the three-month periods ended March 31, 2017 and 2016, respectively.

11. Commitments and Contingencies

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

Sinotau Litigation – NAV4694

On August 31, 2015, Hainan Sinotau Pharmaceutical Co., Ltd. (“Sinotau”) filed a suit for damages, specific performance, and injunctive relief against the Company in the United States District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company’s NAV4694 product candidate and technology. The Company believed the suit was without merit and filed a motion to dismiss the action. In September 2016, the Court denied the motion to dismiss. The Company filed its answer to the complaint and the case is currently in the discovery phase. At this time it is not possible to determine with any degree of certainty the ultimate outcome of this legal proceeding, including making a determination of liability. The Company intends to vigorously defend the case.

CRG Litigation

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company’s primary bank accounts and took possession of \$4.1 million that was on deposit, applying \$3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining \$189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million and no more than \$66 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a \$7 million letter of credit in favor of CRG (at the Company’s cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414’s indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG’s letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. The Texas hearing is currently set for July 3, 2017. See Notes 2 and 10.

Former CEO Arbitration

On May 12, 2016 the Company received a demand for arbitration through the American Arbitration Association, Columbus, Ohio, from Ricardo J. Gonzalez, the Company's then Chief Executive Officer, claiming that he was terminated without cause and, alternatively, that he resigned in accordance with Section 4G of his Employment Agreement pursuant to a notice received by the Company on May 9, 2016. On May 13, 2016, the Company notified Mr. Gonzalez that his failure to undertake responsibilities assigned to him by the Board of Directors and otherwise work after being ordered to do so on multiple occasions constituted an effective resignation, and the Company accepted that resignation. The Company rejected the resignation of Mr. Gonzalez pursuant to Section 4G of his Employment Agreement. Also, the Company notified Mr. Gonzalez that, alternatively, his failure to return to work after the expiration of the cure period provided in his Employment Agreement constituted cause for his termination under his Employment Agreement. Mr. Gonzalez is seeking severance and other amounts claimed to be owed to him under his Employment Agreement. In addition, the Company filed counterclaims against Mr. Gonzalez alleging malfeasance by Mr. Gonzalez in his role as Chief Executive Officer. Mr. Gonzalez has withdrawn his claim for additional severance pursuant to Section 4G of his Employment Agreement, and the Company has withdrawn its counterclaims. An arbitration hearing took place April 3-4, 2017 in Columbus, Ohio, and we are currently awaiting a decision.

FTI Consulting, Inc. Litigation

On October 11, 2016, FTI Consulting, Inc. ("FTI") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in excess of \$782,600 comprised of: (i) \$730,264 for investigative and consulting services FTI alleges to have provided to the Company pursuant to an Engagement Agreement, and (ii) in excess of \$52,337 for purported interest due on unpaid invoices, plus attorneys' fees, costs and expenses. On November 14, 2016, the Company filed an Answer and Counterclaim denying the allegations of the Complaint and seeking damages on its Counterclaim, in an amount to be determined at trial, for intentional overbilling by FTI. On February 7, 2017, a preliminary conference was held by the Court at which time a scheduling order governing discovery was issued. The Court set August 31, 2017 as the deadline for FTI to file a Note of Issue and Certificate of Readiness for trial. The Company intends to vigorously defend the action.

Sinotau Litigation – Tc 99m Tilmanoccept

On February 1, 2017, Navidea filed suit against Sinotau in the U.S. District Court for the Southern District of Ohio. The Company's complaint included claims seeking a declaration of the rights and obligations of the parties to an agreement regarding rights for the Tc 99m tilmanoccept product in China and other claims. The complaint sought a temporary restraining order ("TRO") and preliminary injunction to prevent Sinotau from interfering with the Company's Asset Sale to Cardinal Health 414. On February 3, 2017, the Court granted the TRO and extended it until March 6, 2017. The Asset Sale closed on March 3, 2017. On March 6, the Court dissolved the TRO as moot. The Ohio case remains open because all issues raised in the complaint have not been resolved.

Sinotau also filed a suit against the Company and Cardinal Health 414 in the U.S. District Court for the District of Delaware on February 2, 2017. On February 18, 2017, the Company and Cardinal Health 414 moved to stay the case pending the outcome of the Ohio case. The Court granted the motion on March 1, 2017, and the stay remains in effect.

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. In the case of the CRG litigation, we could still be required to pay up to an additional \$7 million to CRG depending upon the outcome of the Texas litigation, which would have a material negative impact on our financial position. Although the outcome of any litigation is uncertain, in our opinion, the amount of ultimate liability, if any, with respect to any of these actions other than CRG will not materially affect our financial position.

12. Equity Instruments

During the three-month periods ended March 31, 2017 and 2016, we issued 16,406 and 16,918 shares of our common stock valued at \$10,500 and \$20,640 to certain members of our Board of Directors as payment in lieu of cash for their retainer fees.

Also during the three-month period ended March 31, 2017, we issued 707,353 shares of our common stock valued at \$367,812 to our employees as partial payment in lieu of cash for their 2015 and 2016 bonuses.

13. Stock Warrants

In January 2017, Dr. Michael Goldberg, the Company's President and CEO, exercised 5,411,850 of his Series LL warrants in exchange for 5,411,850 shares of our common stock, resulting in proceeds to the Company of \$54,119.

In March 2017, in connection with the Asset Sale, the Company granted to each of Cardinal Health 414 and the University of California, San Diego ("UCSD"), a five-year warrant to purchase up to 10 million shares and 1 million shares, respectively, of the Company's common stock at an exercise price of \$1.50 per share, each of which warrant is subject to anti-dilution and other customary terms and conditions (the "Series NN warrants"). The fair value of the Series NN warrants was calculated using the Black-Scholes model using our five-year historical weekly volatility of 77% and a risk-free rate equal to the five-year treasury constant maturity rate of 2%. The Series NN warrants granted to Cardinal Health 414 had an estimated fair value of \$3.3 million, which was recorded as a reduction of the gain on sale in the consolidated statement of operations for the three-month period ended March 31, 2017. The Series NN warrants granted to UCSD had an estimated fair value of \$334,000, which was recorded as an intangible asset related to the UCSD license in the consolidated balance sheet during the three-month period ended March 31, 2017.

At March 31, 2017, there are 16.9 million warrants outstanding to purchase Navidea's common stock. The warrants are exercisable at prices ranging from \$0.01 to \$3.04 per share with a weighted average exercise price of \$1.19 per share. The warrants have remaining outstanding terms ranging from 1 to 18 years.

In addition, at March 31, 2017, 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. Deferred tax assets and liabilities 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. Deferred tax assets and liabilities 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 deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to the uncertainty surrounding the realization of the deferred tax assets in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance at March 31, 2017 and December 31, 2016.

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, 2017 or December 31, 2016 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, 2017, tax years 2013-2016 remained subject to examination by federal and state tax authorities.

Benefit from income taxes was \$1.5 million for the three-month period ended March 31, 2017, representing an effective tax rate of 33.7%, as compared to \$0 for the three-month period ended March 31, 2016, representing an effective tax rate of 0%. The increase in the effective rate for the period ended March 31, 2017 compared with the same period in 2016 is primarily due to the gain on sale of our Lymphoseek product.

As of March 31, 2017, we had approximately \$123.0 million of federal and \$15.8 million of state net operating loss 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, our R-NAV joint venture (terminated on May 31, 2016), NAV4694 and NAV5001 (license terminated in April 2015), and (ii) therapeutic development programs, including therapeutic applications of our Manocept platform and all development programs undertaken by Macrophage Therapeutics, Inc.

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

Three Months Ended March 31, 2017	<u>Diagnostics</u>	<u>Therapeutics</u>	<u>Corporate</u>	<u>Total</u>
Tc 99m tilmanocept sales revenue:				
United States	\$ —	\$ —	\$ —	\$ —
International	—	—	—	—
Tc 99m tilmanocept license revenue	—	—	—	—
Grant and other revenue	571,362	8,668	—	580,030
Total revenue	<u>571,362</u>	<u>8,668</u>	<u>—</u>	<u>580,030</u>
Cost of goods sold, excluding depreciation and amortization	—	—	—	—
Research and development expenses, excluding depreciation and amortization	413,202	292,072	—	705,274
Selling, general and administrative expenses, excluding depreciation and amortization ⁽¹⁾	—	2,521	2,943,123	2,945,644
Depreciation and amortization ⁽²⁾	—	—	76,790	76,790
Income (loss) from operations ⁽³⁾	<u>158,160</u>	<u>(285,925)</u>	<u>(3,019,913)</u>	<u>(3,147,678)</u>
Other expense	—	—	(1,171,109)	(1,171,109)
Income tax (expense) benefit	(53,254)	96,273	1,411,153	1,454,172
Net income (loss) from continuing operations	104,906	(189,652)	(2,779,869)	(2,864,615)
Loss from discontinued operations, net of tax	(255,861)	—	—	(255,861)
Gain on sale of discontinued operations, net of tax	88,701,501	—	—	88,701,501
Net income (loss)	<u>88,550,546</u>	<u>(189,652)</u>	<u>(2,779,869)</u>	<u>85,581,025</u>
Total assets, net of depreciation and amortization:				
United States	9,692,007	897	23,116,511	32,809,415
International	115,279	—	893	116,172
Capital expenditures	—	—	—	—

Three Months Ended March 31, 2016	Diagnostics	Therapeutics	Corporate	Total
Tc 99m tilmanocept sales revenue:				
United States	\$ —	\$ —	\$ —	\$ —
International	8,800	—	—	8,800
Tc 99m tilmanocept license revenue	254,050	—	—	254,050
Grant and other revenue	685,635	—	—	685,635
Total revenue	<u>948,485</u>	<u>—</u>	<u>—</u>	<u>948,485</u>
Cost of goods sold, excluding depreciation and amortization	1,489	—	—	1,489
Research and development expenses, excluding depreciation and amortization	1,830,471	241,800	—	2,072,271
Selling, general and administrative expenses, excluding depreciation and amortization ⁽¹⁾	—	(598)	2,558,758	2,558,160
Depreciation and amortization ⁽²⁾	—	—	74,966	74,966
Loss from operations ⁽³⁾	<u>(883,475)</u>	<u>(241,202)</u>	<u>(2,633,724)</u>	<u>(3,758,401)</u>
Other income (expense), excluding equity in loss of R-NAV, LLC ⁽⁴⁾	—	—	1,088,824	1,088,824
Equity in loss of R-NAV, LLC	—	—	(12,239)	(12,239)
Net income (loss) from continuing operations	<u>(883,475)</u>	<u>(241,202)</u>	<u>(1,557,139)</u>	<u>(2,681,816)</u>
Loss from discontinued operations, net of tax	<u>(1,004,433)</u>	<u>—</u>	<u>—</u>	<u>(1,004,433)</u>
Net loss	<u>(1,887,908)</u>	<u>(241,202)</u>	<u>(1,557,139)</u>	<u>(3,686,249)</u>
Total assets, net of depreciation and amortization:				
United States	4,273,762	16,515	7,610,817	11,901,094
International	380,982	—	1,605	382,587
Capital expenditures	—	—	1,847	1,847

- (1) General and administrative expenses, excluding depreciation and amortization, represent costs that relate to the general administration of the Company and as such are not currently allocated to our individual reportable segments.
- (2) Depreciation and amortization is reflected in selling, general and administrative expenses (\$76,790 and \$74,966 for the three-month periods ended March 31, 2017 and 2016).
- (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.
- (4) Amounts consist primarily of changes in fair value of financial instruments and losses on debt extinguishment, 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, 2017 and 2016, we paid interest aggregating \$7.3 million \$1.3 million, respectively. During the three-month period ended March 31, 2017, we issued 1 million Series NN warrants to UCSD with an estimated fair value of \$334,000. As discussed in Note 8, the liability for the additional \$200,000 of investments made by Platinum was reclassified to additional paid-in-capital in January 2017.

17. Subsequent Events

The Company has evaluated events and transactions subsequent to March 31, 2017 and through the date these consolidated financial statements were included in this Form 10-Q and filed with the SEC.

On May 4, 2017, the Company executed a 12-month employment agreement with Jed A. Latkin effective May 4, 2017 through May 3, 2018. The employment agreement provides for an annual base salary of \$325,000. In connection with his employment agreement, Mr. Latkin was granted options to purchase 1,000,000 shares of our common stock with vesting terms as follows: (i) 333,334 options with a strike price of \$0.65 will vest on or after May 4, 2017, so long as the closing market price of the underlying common stock equals or exceeds \$0.65; (ii) 333,333 options with a strike price of \$0.75 will vest on or after December 31, 2017, so long as the closing market price of the underlying common stock equals or exceeds \$1.00, and (iii) 333,333 options with a strike price of \$1.00 will vest on or after December 31, 2018, so long as the closing market price of the underlying common stock equals or exceeds \$1.25.

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. 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, among other things:

- general economic and business conditions, both nationally and in our markets;
- our history of losses and uncertainty of future profitability;
- the final outcome of the CRG litigation in Texas;
- 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 expectations and estimates concerning future financial performance, financing plans and the impact of competition;
- our ability to raise capital sufficient to fund our development and commercialization programs;
- our ability to implement our growth strategy;
- anticipated trends in our business;
- advances in technologies; 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,” and similar expressions to identify forward-looking statements.

We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

The Company

Navidea Biopharmaceuticals, Inc. (“Navidea,” the “Company,” or “we”), a Delaware corporation (NYSE MKT: 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 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 Lymphoseek® (technetium Tc 99m tilmanocept) injection, the first product developed and commercialized by Navidea based on the platform.

On March 3, 2017, pursuant to an Asset Purchase Agreement dated November 23, 2016, (the “Purchase Agreement”), the Company completed its previously announced 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 (the “Business”), including the Company’s radioactive diagnostic agent marketed under the Lymphoseek® trademark for current approved indications by the U.S. Food and Drug Administration (“FDA”) and similar indications approved by the FDA in the future (the “Product”), in Canada, Mexico and the United States (the “Territory”) (giving effect to the License-Back described below and excluding certain assets specifically retained by the Company) (the “Asset Sale”). Such assets sold in the Asset Sale consist primarily of, without limitation, (i) intellectual property used in or reasonably necessary for the conduct of the Business, (ii) inventory of, and customer, distribution, and product manufacturing agreements related to, the Business, (iii) all product registrations related to the Product, including the new drug application approved by the FDA for the Product and all regulatory submissions in the United States that have been made with respect to the Product and all Health Canada regulatory submissions and, in each case, all files and records related thereto, (iv) all related clinical trials and clinical trial authorizations and all files and records related thereto, and (v) all right, title and interest in and to the Product, as specified in the Purchase Agreement (the “Acquired Assets”).

In connection with the closing of the Asset Sale, the Company entered into a License-Back Agreement (the "License-Back") with Cardinal Health 414. Pursuant to the License-Back, Cardinal Health 414 granted to the Company a sublicensable (subject to conditions) and royalty-free license to use certain intellectual property rights included in the Acquired Assets and owned by Cardinal Health 414 as of the closing of the Asset Sale to the extent necessary for the Company to (i) on an exclusive basis, subject to certain conditions, develop, manufacture, market, sell and distribute new pharmaceutical and other products that are not Competing Products (as defined in the License-Back), and (ii) on a non-exclusive basis, develop, manufacture, market, sell and distribute the Product throughout the world other than in the Territory. Subject to the Company's compliance with certain restrictions in the License-Back, the License-Back also restricts Cardinal Health 414 from using the intellectual property rights included in the Acquired Assets to develop, manufacture, market, sell, or distribute any product other than the Product or other product that (a) accumulates in lymphatic tissue or tumor-draining lymph nodes for the purpose of (1) lymphatic mapping or (2) identifying the existence, location or staging of cancer in a body, or (b) provides for or facilitates any test or procedure that is reasonably substitutable for any test or procedure provided for or facilitated by the Product. Pursuant to the License-Back and subject to rights under existing agreements, Cardinal Health 414 was given a right of first offer to market, sell and/or market any new products developed from the intellectual property rights licensed by Cardinal Health 414 to the Company by the License-Back.

As part of the Asset Sale, the Company and Cardinal Health 414 also entered into ancillary agreements providing for transitional services and other arrangements. The Company amended and restated its license agreement with The Regents of the University of California, San Diego ("UCSD") pursuant to which UCSD granted a license to the Company to exploit certain intellectual property rights owned by UCSD and, separately, Cardinal Health 414 entered into a license agreement with UCSD pursuant to which UCSD granted a license to Cardinal Health 414 to exploit certain intellectual property rights owned by UCSD for Cardinal Health 414 to sell the Product in the Territory.

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 million of guaranteed earnout payments as part of the CRG settlement (described below in Part II, Item 1 – Legal Proceedings), (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 additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG (described below in Part II, Item 1 – Legal Proceedings).

Upon closing of the Asset Sale, the Supply and Distribution Agreement, dated November 15, 2007 (as amended, the "Supply and Distribution Agreement"), between Cardinal Health 414 and the Company was terminated and, as a result, the provisions thereof are of no further force or effect (other than any indemnification, payment, notification or data sharing obligations which survive the termination). At the closing of the Asset Sale, Cardinal Health 414 paid to the Company \$1.2 million, as an estimate of the accrued revenue sharing payments owed to the Company as of the closing date, net of prior payments.

The Asset Sale to Cardinal Health 414 in March 2017 significantly improved our financial condition and our ability to continue as a going concern. The Company also continues working to establish new sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to levels that can be supported by our revenues.

Other than Tc 99m 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.

Product Line Overview

Our primary development efforts over the last few years have been focused on diagnostic products, including Lymphoseek which was sold to Cardinal Health 414 in March 2017, as well as other diagnostic and therapeutic line extensions based on our Manocept platform.

The flexible and versatile Manocept platform acts as an engine for the design of targeted imaging molecules 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. We have active clinical diagnostic programs in four diseases representing both major macrophage activation states.

Cardiovascular Disease ("CV") – We have completed a nine-subject study to evaluate diagnostic imaging of emerging atherosclerosis plaque with the Tc 99m tilmanocept product dosed subcutaneously. The results of this study were recently published in early release in the *Journal of Infectious Diseases* in January 2017, confirming that the Tc 99m tilmanocept product can both quantitatively and qualitatively target non-calcified plaque in the aortic arch (NIH/NHLBI Grant 1 R43 HL127846-01). We have applied for follow-on NIH/NHLBI support to fund additional clinical studies. These studies are currently under development and design for both Phase 1 and Phase 2 trials.

Rheumatoid Arthritis (“RA”) – We have initiated two dose escalation studies in RA. The first study, now complete, included 18 subjects (9 with active disease and 9 controls) who were dosed subcutaneously with Tc 99m tilmanocept. In addition, based on completion of extensive preclinical dosing studies pursuant to our dialog with the FDA, we have initiated and partially completed a study dosing the Tc 99m tilmanocept product intravenously (“IV”). These studies have been supported through a Small Business Innovation Research (“SBIR”) grant (NIH/NIAMSD Grant 1 R44 AR067583-01A1).

Kaposi’s Sarcoma (“KS”) – Although we initiated and completed a study of KS in 2015, we received additional funding from the National Institutes of Health (“NIH”) in 2016 to continue studies in this disease. The new support not only continues the imaging of cutaneous elements of this disease but expands this to imaging of visceral disease via IV administration of Tc 99m tilmanocept (NIH/NCI 1 R44 CA192859-01A1). Additionally, we received funding to support the therapeutic initiative for KS employing the MT-1002 agent under current evaluation. The Company has already completed a portion of the Phase 1 SBIR portion of this award (1 R44 CA206788-01).

Colorectal Cancer (“CRC”) and Synchronous Liver Metastases – During the first quarter of 2017, we initiated an imaging study in subjects with CRC and liver metastases via IV administration of Tc 99m tilmanocept. This study will enroll up to 12 subjects with dose modification. This study is supported through a SBIR grant (1 R44 CA1962783-01A1).

Based on performance in these very large imaging market opportunities the Company anticipates continued investment in these programs including initiating studies designed to obtain new approvals for the Tc 99m tilmanocept product.

The Company has completed preclinical studies employing both MT 1000-class and 2000-class therapeutic conjugates of Manocept. The highly positive results from these studies are indicative of Manocept’s specific targeting supported by its notable binding affinity to CD206 receptors. This high 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. Our efforts in this area were further supported by the 2015 formation of MT, a majority-owned subsidiary that was formed specifically to explore therapeutic applications for the Manocept platform.

MT has been set up to pursue the drug delivery model. This model enables the Company to leverage its technology over many potential therapeutic 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 continue to seek to partner or out-license NAV4694. The NAV5001 sublicense was terminated in April 2015.

Tc 99m Tilmanocept – Status in Europe

The European Commission (“EC”) granted marketing authorization for Tc 99m tilmanocept in the EU in November 2014. We recently completed manufacturing validation activities on a finished drug product contract manufacturing facility to support the Company’s supply chain, primarily in Europe. This facility will produce a reduced-mass vial for which we received approval from the European Medicines Agency (“EMA”) in September 2016. Our partner, SpePharm AG (an affiliate of Norgine BV), is currently completing the customary pre-launch market access activities to support commercial launch in the EU during the first half of 2017. Following the January 2017 transfer of the Tc 99m tilmanocept Marketing Authorization to SpePharm, we are in the process of transferring responsibility for manufacturing the reduced-mass vial for the EU market to SpePharm.

Manocept Platform - Diagnostics and Therapeutics Background

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. Activated macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. This flexible and versatile platform serves as an engine for purpose-built molecules that may significantly impact patient care by providing enhanced diagnostic accuracy, clinical decision-making, and target-specific treatment. This disease-targeted drug platform provides the capability to utilize a breadth of diagnostic modalities, including SPECT, PET, gamma-scan (both imaging and topical), 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-based disorders. The FDA-approved sentinel node/lymphatic mapping agent, Tc 99m tilmanocept, is representative of the ability to successfully exploit this mechanism to develop powerful new products.

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 perhaps 700 million worldwide, making macrophage-mediated diseases an area of remarkable clinical importance. There are many recognized disorders having macrophage involvement, including RA, atherosclerosis/vulnerable plaque, nonalcoholic steatohepatitis ("NASH"), inflammatory bowel disease, systemic lupus erythematosus, KS, and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, CNS diseases, and inflammation.

Manocept Platform – Immuno-Diagnostics Clinical Data

Rheumatoid Arthritis

In conjunction with the agreed submission of an investigational new drug ("IND") amendment for IV administration of tilmanocept to the FDA, we initiated a multi-center Phase 1/2 registrational trial employing IV administration to evaluate tilmanocept for the primary diagnosis of RA and to aid in the differential diagnosis of RA from other types of inflammatory arthritis. The first subject was dosed and imaged in February 2017. This study will enroll up to 30 subjects with dose escalation (ClinicalTrials.gov Identifier:NCT02865434; Study supported by NIH/NIAMSD Grant 1 R44 AR067583-01A1).

Cardiovascular Disease

Results of our studies to date (ClinicalTrials.gov Identifier:NCT02542371) provide strong evidence of the potential of Tc 99m tilmanocept to accumulate in high risk morphology plaques, the ability to make preliminary comparisons of aortic Tc 99m tilmanocept uptake by SPECT/CT in clinically symptomatic patients vs. healthy age-matched subjects, and to evaluate the ability of Tc 99m tilmanocept to identify the same aortic atherosclerotic plaques that are identified by contrast enhanced coronary computed tomography angiography and/or PET/CT.

Other Immuno-Diagnostic Applications

The Company has received an award for a Fast Track SBIR grant providing for up to \$1.8 million from the NIH's National Cancer Institute to fund preclinical studies examining the safety of IV injection of Tc99m tilmanocept, a Manocept platform product, followed by a clinical study providing the initial evaluation of the safety and efficacy of SPECT imaging studies with IV Tc99m tilmanocept to identify and quantify both skin- and organ-associated KS lesions in human patients. The grant is awarded in two parts with the potential for total grant money of up to \$1.8 million over two and a half years. The first six-month funding segment of \$300,000, which has already been awarded, is expected to enable Navidea to secure necessary collaborations and Institutional Review Board approvals. The second funding segment could provide for up to an additional \$1.5 million to be used to accrue participants, perform the Phase 1/2 study and perform data analyses to confirm the safety and effectiveness of intravenously administered Tc99m tilmanocept. We have received IRB approval of the clinical protocol, and we plan to initiate a Phase 1/2 clinical study in KS during 2017.

Macrophage Therapeutics Background

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.

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

The novel MT-1002 construct is designed to specifically deliver doxorubicin, a chemotoxin, which can kill KS tumor cells and their tumor-associated macrophages potentially altering the course of cancer. KS is a serious and potentially life threatening illness in persons infected with HIV and the third leading cause of death in this population worldwide. The prognosis for patients with KS is poor with high probabilities for mortality and greatly diminished quality of life. The funds for this Fast Track grant will be released in three parts, which together have the potential to provide up to \$1.8 million in resources over 2.5 years with the goal of completing an 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 will provide \$232,000 to support analyses including in vitro and cell culture studies and will be followed by Part 2 and 3 animal testing studies. If successful, 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 selected in human KS patients.

Navidea and MT continue 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.

Navidea and MT 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 Navidea and MT continue this work funded by the NIH/NIAID and NCI.

Nonalcoholic fatty liver disease (“NAFLD”) is a spectrum of liver disorders and is defined by the presence of steatosis in more than 5% of hepatocytes with little or no alcohol consumption. Nonalcoholic steatohepatitis (“NASH”) is the most extreme form of NAFLD. A major characteristic of NASH involves cells undergoing lipotoxicity, releasing endogenous signals prompting the accumulation of various macrophages to assess the damage. Studies have shown that levels of endogenous molecular inflammatory signals positively correlate with inflammation, hepatocyte ballooning, and other NAFLD symptoms. Navidea and MT have developed a molecular delivery technology capable of targeting only the disease-causing macrophages by selectively binding to the CD206 receptor. Selective binding and efficient delivery of this agent mitigates the potential of affecting the neighboring cells or interfering more broadly with the normal function of the immune system.

We have completed three in vivo studies employing our MT-1002 and MT-2002 Manocept conjugates in a well-established 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 vs. control in the later dosing arm of the study. Liver weights were not different during any phase of the study between control and agent-treated groups, nor was there any evidence of damage to the roughly 30% of the liver made up of un-activated macrophages called Kupffer cells. MT-1002 and MT-2002 both significantly reduced key disease assessment parameters in the in vivo STAM™ NASH model. We believe these agents present themselves as potential clinically effective candidates for further evaluation. We continue to use this model to further assess the activity of our agents.

Navidea and MT 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 Navidea and MT continue this work funded by the NIH/NIAID and NCI.

We have completed a series of predictive in vitro screening tests of the MT-1002 and MT-2002 therapeutic conjugates against the Zika and Dengue viruses, which included infectivity and viral replication inhibition effectiveness as well as dose finding studies and mechanisms of action, the latter based on conjugate structures. We have also completed a series of predictive in vivo screening tests of the MT-1002 and MT-2002 therapeutic conjugates against Leishmaniosis, which included host cell targeting and killing effectiveness as well as dose finding studies and mechanisms of action. The results from these evaluations were positive and have provided a basis for moving forward with in vivo testing of the selected conjugates. We have selected a collaborator for these in vivo studies, which will take place over the next four months. We will provide updates as information becomes available on future testing.

NAV4694 (Candidate for Divestiture)

NAV4694 is a fluorine-18 (“F-18”) labeled PET imaging agent being developed as an aid in the imaging and evaluation of patients with signs or symptoms of Alzheimer’s disease (“AD”) and mild cognitive impairment (“MCI”). NAV4694 binds to beta-amyloid deposits in the brain that can then be imaged in PET scans. Amyloid plaque pathology is a required feature of AD and the presence of amyloid pathology is a supportive feature for diagnosis of probable AD. Patients who are negative for amyloid pathology do not have AD. NAV4694 has been studied in rigorous pre-clinical studies and clinical trials in humans. Clinical studies through Phase 3 have included subjects with MCI, suspected AD patients, and healthy volunteers. Results suggest that NAV4694 has the potential ability to image patients quickly and safely with high sensitivity and specificity.

In May 2014, the Board of Directors made the decision to refocus the Company's resources to better align the funding of our pipeline programs with the expected growth in Tc 99m tilmanocept revenue. This realignment primarily involved reducing our near-term support for our neurological product candidates, including NAV4694, as we sought a development partner or partners for these programs. The Company is currently engaged in discussions related to the potential partnering or divestiture of NAV4694. We continue to have active interest from potential partners or acquirers; however, our negotiations have experienced delays due in large part to litigation brought by one of the potential partners. The Company believed the suit was without merit and filed a motion to dismiss the action. In September 2016, the court determined that there was enough evidence to proceed with the case and denied Navidea’s motion to dismiss. Navidea is currently preparing for a trial which is expected to take place within the next twelve months. At this time it is not possible to determine with any degree of certainty the ultimate outcome of this legal proceeding, including making a determination of liability.

NAV5001 (In-License Terminated)

NAV5001 is an iodine-123 (I-123) labeled SPECT imaging agent being developed as an aid in the diagnosis of Parkinson’s disease (PD) and other movement disorders, with potential use as a diagnostic aid in dementia. The agent binds to the dopamine transporter (DAT) on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a hallmark of PD. In addition to its potential use as an aid in the differential diagnosis of PD and movement disorders, NAV5001 may also be useful in the diagnosis of Dementia with Lewy Bodies, one of the most common forms of dementia after AD.

In May 2014, the Board of Directors made the decision to refocus the Company's resources to better align the funding of our pipeline programs with the expected growth in Lymphoseek revenue. This realignment primarily involved reducing our near-term support for our neurological product candidates, including NAV5001.

In April 2015, the Company entered into an agreement with Alseres to terminate the sub-license agreement dated July 31, 2012 for research, development and commercialization of NAV5001. Under the terms of this agreement, Navidea transferred all regulatory, clinical and manufacturing-related data related to NAV5001 to Alseres. Alseres agreed to reimburse Navidea for any incurred maintenance costs of the contract manufacturer retroactive to March 1, 2015. In addition, Navidea has supplied clinical support services for NAV5001 on a cost-plus reimbursement basis. However, to this point, Alseres has been unsuccessful in raising the funds necessary to restart the program and reimburse Navidea. As a result, we have taken steps to end our obligations under the agreement and notified Alseres that we consider them in breach of the agreement. We are in the process of trying to recover the funds we expended complying with our obligations under the termination agreement.

Outlook

Our operating expenses in recent years have been focused primarily on support of Tc 99m tilmanocept, our Manocept platform, and NAV4694 and NAV5001 product development. We incurred approximately \$8.9 million, \$12.8 million and \$16.8 million in total on research and development activities during the years ended December 31, 2016, 2015 and 2014, 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,	
	2017	2016
Lymphoseek	\$ 241,687	\$ 585,195
Manocept Platform	318,688	153,841
Macrophage Therapeutics	252,073	187,583
NAV4694 (b)	(553,743)	564,558
NAV5001	—	54,424

(a) Amounts reflect projects included in discontinued operations in the consolidated statements of operations. Certain development program expenditures were offset by grant reimbursement revenues totaling \$556,000 and \$608,000 during the three-month periods ended March 31, 2017 and 2016, respectively.

(b) Changes in cost estimates resulted in the reversal of certain previously accrued expenses related to the NAV4694 development program during the three-month period ended March 31, 2017.

We expect to continue the advancement of our efforts with our Manocept platform during 2017. The divestiture of NAV5001 and the suspension of active patient accrual in our NAV4694 trials have decreased our development costs over the past year, however, we continue to incur costs to maintain the trials while we complete our partnering/divestiture activities. We expect our total research and development expenses, including both out-of-pocket charges as well as internal headcount and support costs, to be lower in 2017 than in 2016. This estimate excludes charges related to our subsidiary, Macrophage Therapeutics, Inc., which are currently to be funded separately.

Tc 99m tilmanocept is approved by the EMA for use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity in the EU. There can be no assurance that Tc 99m tilmanocept will achieve regulatory approval in any other market outside the EU, or if approved in those markets, that it will achieve market acceptance in the EU or any other market.

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 Tc 99m tilmanocept in the EU and other markets. We continue to evaluate existing and emerging data on the potential use of Manocept-related agents in the diagnosis and disease-staging of disorders in which macrophages are involved, such as KS, RA, vulnerable plaque/atherosclerosis, TB 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 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." 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 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 additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG.

We recorded a net gain on the sale of the Business of \$88.7 million for the three months ended March 31, 2017, including \$16.5 in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by \$3.3 million in estimated fair value of warrants issued to Cardinal Health 414, \$2.0 million in legal and other fees related to the sale, \$800,000 in net balance sheet dispositions and write-offs, and \$4.6 million in estimated taxes. Our consolidated balance sheets and statements of operations have been reclassified, as required, for all periods presented to reflect the Business as a discontinued operation. Cash flows associated with the operation of the Business have been combined with operating, investing and financing cash flows, as appropriate, in our consolidated statements of cash flows.

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, 2017 and 2016

Tc 99m Tilmanocept License Revenue. During the first quarter of 2016, we recognized \$254,000 of the \$2.0 million non-refundable upfront payment received by the Company related to the Tc 99m Tilmanocept license and distribution agreement for Europe, which the Company was recognizing on a straight-line basis over two years. No license revenue was recognized during the first quarter of 2017.

Grant and Other Revenue. During the first quarter of 2017, we recognized \$580,000 of grant and other revenue as compared to \$686,000 in the first quarter of 2016. Grant revenue during the first quarter of 2017 was primarily related to SBIR grants from the NIH supporting Manocept and Tc 99m Tilmanocept development. Grant revenue during the first quarter of 2016 was primarily related to SBIR grants from the NIH supporting NAV4694, Tc 99m Tilmanocept and Manocept development.

Research and Development Expenses. Research and development expenses decreased \$1.4 million, or 66%, to \$705,000 during the first quarter of 2017 from \$2.1 million during the same period in 2016. The decrease was primarily due to net decreases in drug project expenses related to (i) decreased NAV4694 development costs of \$1.1 million including decreased manufacturing-related activities, clinical trial costs and licensing costs while we continued our efforts to divest the program; (ii) decreased Tc 99m Tilmanocept development costs of \$178,000 including decreased regulatory costs, manufacturing-related activities and preclinical testing; and (iii) decreased NAV5001 development costs of \$54,000 including decreased manufacturing-related activities and clinical trial costs; offset by (iv) increased Manocept development costs of \$165,000 including increased clinical trial costs, offset by decreased pre-clinical testing; and (v) increased therapeutics development costs of \$64,000 including increased manufacturing-related activities and preclinical testing, offset by decreased consulting costs. The net decrease in research and development expenses also included decreased compensation including incentive-based awards and other expenses related to net decreased headcount of \$247,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$389,000, or 15%, to \$3.0 million during the first quarter of 2017 from \$2.6 million during the same period in 2016. The net increase was primarily due to increased legal and professional services of \$579,000, offset by decreased costs for investor relations services of \$104,000 coupled with decreased general and administrative headcount of \$97,000.

Other Income (Expense). Other expense, net, was \$1.2 million during the first quarter of 2017 as compared to other income, net of \$1.1 million during the same period in 2016. We recorded a loss on extinguishment of the CRG debt of \$1.3 million during the first quarter of 2017. Also during the first quarter of 2017, we recognized interest income of \$30,000 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 quarters of 2017 and 2016, we recorded non-cash income of \$140,000 and \$1.1 million, respectively, related to changes in the estimated fair value of financial instruments.

Liquidity and Capital Resources

Cash balances increased to \$13.4 million at March 31, 2017 from \$1.5 million at December 31, 2016. The net increase was primarily due to net cash received for the Asset Sale to Cardinal Health 414, offset by payments made on the CRG and Platinum debts coupled with cash used to fund our operations.

All of our material assets were pledged as collateral for our borrowings under the CRG Loan Agreement. In addition to the security interest in our assets, the CRG Loan Agreement carried covenants that imposed significant requirements on us. An event of default entitled CRG to accelerate the maturity of our indebtedness, increase the interest rate from 14% to the default rate of 18% per annum, and invoke other remedies available to it under the loan agreement and the related security agreement.

As previously described, on March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Texas hearing is currently set for July 3, 2017.

In addition, the Platinum Loan Agreement carries standard non-financial covenants typical for commercial loan agreements that impose significant requirements on us. Our ability to comply with these provisions may be affected by changes in our business condition or results of our operations, or other events beyond our control. The breach of any of these covenants would result in a default under the Platinum Loan Agreement, permitting Platinum to accelerate the maturity of the debt. Such actions by Platinum could materially adversely affect our operations, results of operations and financial condition, including causing us to curtail our product development activities. We are currently in compliance with all covenants under the Platinum Loan Agreement.

In connection with the closing of the Asset Sale to Cardinal Health 414, 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, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

As of March 31, 2017, the outstanding principal balance of the Platinum Note was approximately \$1.9 million.

Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern has been alleviated. Although we could still be required to pay up to an additional \$7 million to CRG depending upon the outcome of the Texas litigation, the Company's management believes that the Company will be able to continue as a going concern for at least twelve months following the issuance of this Quarterly Report on Form 10-Q.

Operating Activities. Cash provided by operations was \$66.3 million during the first quarter of 2017 compared to \$1.7 million used during the same period in 2016.

In connection with the Asset Sale, 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 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 additional purchase price) to the Company based on net sales derived from the purchased Product subject, in each case, to Cardinal Health 414's right to off-set. In no event will the sum of all earnout payments, as further described in the Purchase Agreement, exceed \$230 million over a period of ten years, of which \$20.1 million are guaranteed payments for the three years immediately after closing of the Asset Sale. At the closing of the Asset Sale, \$3 million of such earnout payments were advanced by Cardinal Health 414 to the Company, and paid to CRG as part of the Deposit Amount paid to CRG.

We recorded a net gain on the sale of the Business of \$88.7 million for the three months ended March 31, 2017, including \$16.5 in guaranteed consideration, which was discounted to the present value of future cash flows. The proceeds were offset by \$3.3 million in estimated fair value of warrants issued to Cardinal Health 414, \$2.0 million in legal and other fees related to the sale, \$800,000 in net balance sheet dispositions and write-offs, and \$4.6 million in estimated taxes.

Accounts and other receivables increased to \$7.2 million at March 31, 2017 from \$203,000 at December 31, 2016, primarily related to the current portion of the guaranteed earnout due from Cardinal, which was discounted and recorded at present value.

Inventory levels decreased to less than \$1,000 at March 31, 2017 from \$96,000 at December 31, 2016, primarily due to the use of materials for European manufacturing development and production. We expect inventory levels to remain minimal during the remainder of 2017 as we transition European manufacturing to our distribution partner.

Prepaid expenses and other current assets increased to \$1.1 million at March 31, 2017 from \$842,000 at December 31, 2016, primarily due to additional prepaid insurance and legal retainers, offset by normal amortization of prepaid insurance.

Accounts payable decreased to \$3.1 million at March 31, 2017 from \$5.2 million at December 31, 2016, primarily driven by net decreased payables due to legal and professional services, NAV4694, regulatory and operations vendors, offset by net increased payables due to MT vendors. Accrued liabilities and other current liabilities decreased to \$1.2 million at March 31, 2017 from \$7.9 million at December 31, 2016, primarily driven by decreased accruals for interest, bonuses, NAV4694, legal and professional services, and Macrophage Therapeutics costs, offset by increased accruals for Manoccept development costs. Our payable and accrual balances will continue to fluctuate but will likely decrease overall as we continue to decrease our level of development activity related to NAV4694, offset by planned increases in development activity related to the Manoccept platform.

Assets associated with discontinued operations decreased to \$0 at March 31, 2017 from \$3.2 million at December 31, 2016, and liabilities associated with discontinued operations decreased to \$3.6 million at March 31, 2017 from \$4.9 million at December 31, 2016. Decreases in both assets and liabilities associated with discontinued operations were primarily due to the Asset Sale to Cardinal Health 414 in March 2017.

Investing Activities. Investing activities used \$0 during the first quarter of 2017 compared to \$2,000 during the same period in 2016. Capital expenditures of \$2,000 during the first quarter of 2016 were primarily for computer equipment. We expect our overall capital expenditures for the remainder of 2017 will be higher than for the same period in 2016 related to our planned office move.

Financing Activities. Financing activities used \$54.4 million during the first quarter of 2017 compared to \$1,000 during the same period in 2016. The \$54.4 million used by financing activities in the first quarter of 2017 consisted primarily of principal payments on the CRG and Platinum notes payable of \$59.5 million, offset by the release of restricted cash of \$5.0 million and proceeds from issuance of common stock of \$54,000.

Capital Royalty Group Debt

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid \$59 million of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the actual amount owed by the Company to CRG under the CRG Loan Documents. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million and no more than \$66 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a \$7 million letter of credit in favor of CRG (at the Company's cost and expense, deducted from the closing proceeds paid to the Company, and subject to Cardinal Health 414's indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG's letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. The Texas hearing is currently set for July 3, 2017.

Platinum Credit Facility

In connection with the closing of the Asset Sale to Cardinal Health 414, 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, to the extent of such payment, were transferred by Platinum-Montaur to PPCO. The Company was informed by PPVA that it was the owner of the balance of the Platinum-Montaur loan. Such balance of approximately \$1.9 million was due upon closing of the Asset Sale but withheld by the Company and not paid to anyone as it is subject to competing claims of ownership by both Dr. Michael Goldberg, the Company's President and Chief Executive Officer, and PPVA.

As of March 31, 2017, the outstanding principal balance of the Platinum Note was approximately \$1.9 million.

Summary

Our future liquidity and capital requirements will depend on a number of factors, including the final outcome of the CRG litigation which could potentially result in payment of up to an additional \$7 million to CRG, our ability 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, and intellectual property protection.

Following the completion of the Asset Sale to Cardinal Health 414 and the repayment of a majority of our indebtedness, we believe that substantial doubt about the Company's financial position and ability to continue as a going concern has been removed. The Company is also working to establish additional sources of non-dilutive funding, including collaborations and grant funding that can augment the balance sheet as the Company works to reduce spending to sustainable levels. Substantial progress on the Manocept platform has resulted in several promising opportunities.

We plan to focus our resources for the remainder of 2017 primarily on defending our position related to CRG's claims of default and development of products based on the Manocept platform. Although management believes that it will be able to achieve these objectives, they are subject to a number of variables beyond our control, including the outcome of the remaining CRG litigation, 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 there can be no assurance that we will be able to achieve our objective of bringing our expenses in line with our revenues, and we may need to seek additional debt or equity financing if we cannot achieve that objective in a timely manner.

During 2016 and 2017 to date, we continued making limited investment in the NAV4694 clinical trial process based on our expectation that we will be successful in ultimately securing a partnership that will provide us some level of return on this investment which is incremental to the carrying costs we are presently incurring. However, there can be no assurance that the partnership discussions in which we are engaged will yield the level of return we are anticipating.

We will continue to evaluate our time lines, strategic needs, and balance sheet requirements. There can be no assurance that if we attempt to raise additional capital through debt, royalty, equity or otherwise, we will be successful in doing so on terms acceptable to the Company, or at all. Further, there can be no assurance that we will be able to gain access and/or be able to execute on securing new sources of funding, 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.

Recent Accounting Standards

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business*. ASU 2017-01 provides a screen to determine when a set of assets and activities (collectively, a "set") is not a business. The screen requires that when substantially all of the fair market value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, ASU 2017-01 (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output, and (2) removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 is effective for public business entities for annual periods beginning after December 15, 2017, including interim periods within those periods. ASU 2017-01 should be applied prospectively on or after the effective date. No disclosures are required at transition. Early adoption is permitted for certain transactions as described in ASU 2017-01. Management is currently evaluating the impact that the adoption of ASU 2017-01 will have on our consolidated financial statements.

Critical Accounting Policies

We base our management's discussion and analysis of financial condition and results of operations, as well as disclosures included elsewhere in this Quarterly Report on Form 10-Q, upon our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We describe our significant accounting policies in the notes to the audited consolidated financial statements contained in our Annual Report on Form 10-K. 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 earn additional revenues related to our licensing and distribution agreements. The terms of these agreements may include payment to us of non-refundable upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. We recognize a contingent milestone payment as revenue in its entirety upon our achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

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

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 is estimated on the date of grant using the Black-Scholes option pricing model to value 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. We estimate the expected term based on the contractual term of the awards and employees' exercise and expected post-vesting termination behavior. The restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the estimated life of the award.

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

- *Fair Value of Financial Instruments.* Certain of our notes payable are required to be recorded at fair value. The estimated fair value of our debt is calculated using a discounted cash flow analysis as well as a probability-weighted Monte Carlo simulation. These valuation methods include Level 3 inputs such as the estimated current market interest rate for similar instruments with similar creditworthiness. For the debt recorded at fair value, unrealized gains and losses on the fair value of the debt are classified in other expenses as a change in the fair value of financial instruments in the consolidated statements of operations.
- *Fair Value of Warrants.* We estimate the fair value of warrants using the Black-Scholes model, which is affected by our stock price and warrant exercise price, as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility and risk-free interest rate.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. As of March 31, 2017, our \$13.4 million in cash was primarily invested in interest-bearing money market accounts. Due to the low interest rates being realized on these accounts, we believe that a hypothetical 10% increase or decrease in market interest rates would not have a material impact on our consolidated financial position, results of operations or cash flows.

We also have exposure to changes in interest rates on our variable-rate debt obligations. As of March 31, 2017, the interest rate on certain of our debt obligations was the greater of: (a) the U.S. prime rate as reported in The Wall Street Journal plus 6.75%, and (b) 10.0%; both of the above rates reduced by 600 basis points (effective interest rate as of March 31, 2017 was 8.125%). Based on the amount of our variable-rate borrowings at March 31, 2017, which totaled approximately \$1.9 million, an immediate one percentage point increase in the U.S. prime rate would increase our annual interest expense by approximately \$19,000. This estimate assumes that the amount of variable rate borrowings remains constant for an annual period and that the interest rate change occurs at the beginning of the period. Because our debt obligations are currently subject to the minimum interest rates defined in the loan agreement, a decrease in the U.S. prime rate would not affect our annual interest expense.

Foreign Currency Exchange Rate Risk. We do not currently have material foreign currency exposure related to our assets as the majority are denominated in U.S. currency and our foreign-currency based transaction exchange risk is not material. For the three-month periods ended March 31, 2017 and 2016, we recorded foreign currency transaction losses of approximately \$19,000 and \$35,000, respectively.

Equity Price Risk. We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. The fair value of our warrant liabilities is determined using various inputs and assumptions, several of which are based on a survey of peer group companies since the warrants are exercisable for common stock of a non-public subsidiary company. As of March 31, 2017, we had approximately \$63,000 of derivative liabilities recorded on our balance sheet related to outstanding MT warrants. Due to the relatively low valuation of the MT warrants, a hypothetical 50% change in our stock price would not have a material effect on the consolidated financial statements.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized, and reported within the specified time periods. As a part of these controls, our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of March 31, 2017. 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. Based on our evaluation, our management has concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed and are effective.

Our management, including our Chief Executive Officer and 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, the 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 generally accepted accounting principles 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.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. As of December 31, 2016, we identified the following material weaknesses:

- The Company did not maintain adequate controls to ensure that information pertinent to the Company's operations were analyzed and communicated by and between financial and non-financial management personnel of the Company. Management has concluded that this control deficiency represented a material weakness.
- The Company did not maintain effective oversight of the Company's external financial reporting and internal control over financial reporting by the Company's Audit Committee. Management has concluded that this control deficiency represented a material weakness.

There were no material adjustments to our current or previously filed interim consolidated financial statements during the year ended December 31, 2016 as a result of these material weaknesses. However, management believes there is a reasonable possibility that these control deficiencies, if uncorrected, could result in material misstatements in the annual or interim consolidated financial statements that would not be prevented or detected in a timely manner. Accordingly, we determined that these control deficiencies constitute material weaknesses.

Changes in Control Over Financial Reporting

Following identification of these material weaknesses, we have worked diligently to improve communication between management and the Board of Directors, including committees. We have taken steps to (i) ensure adequate communication between management, the Board of Directors, and its committees, and (ii) educate the Board of Directors, including its committees, about their role in maintaining effective oversight of the Company's financial reporting processes. As a result, our management considers the material weaknesses to be corrected.

Except for the change noted above, during the quarter ended March 31, 2017, there were no other 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

Sinotau Litigation – NAV4694

On August 31, 2015, Hainan Sinotau Pharmaceutical Co., Ltd. (“Sinotau”) filed a suit for damages, specific performance, and injunctive relief against the Company in the United States District Court for the District of Massachusetts alleging breach of a letter of intent for licensing to Sinotau of the Company’s NAV4694 product candidate and technology. The Company believed the suit was without merit and filed a motion to dismiss the action. In September 2016, the Court denied the motion to dismiss. The Company filed its answer to the complaint and the case is currently in the discovery phase. At this time it is not possible to determine with any degree of certainty the ultimate outcome of this legal proceeding, including making a determination of liability. The Company intends to vigorously defend the case.

CRG Litigation

During the course of 2016, CRG alleged multiple claims of default on the CRG Loan Agreement, and filed suit in the District Court of Harris County, Texas. On June 22, 2016, CRG exercised control over one of the Company’s primary bank accounts and took possession of \$4.1 million that was on deposit, applying \$3.9 million of the cash to various fees, including collection fees, a prepayment premium and an end-of-term fee. The remaining \$189,000 was applied to the principal balance of the debt. Multiple motions, actions and hearings followed over the remainder of 2016 and into 2017.

On March 3, 2017, the Company entered into a Global Settlement Agreement with MT, CRG, and Cardinal Health 414 to effectuate the terms of a settlement previously entered into by the parties on February 22, 2017. In accordance with the Global Settlement Agreement, on March 3, 2017, the Company repaid the \$59 million Deposit Amount of its alleged indebtedness and other obligations outstanding under the CRG Term Loan. Concurrently with payment of the Deposit Amount, CRG released all liens and security interests granted under the CRG Loan Documents and the CRG Loan Documents were terminated and are of no further force or effect; provided, however, that, notwithstanding the foregoing, the Company and CRG agreed to continue with their proceeding pending in The District Court of Harris County, Texas to fully and finally determine the Final Payoff Amount. The Company and CRG further agreed that the Final Payoff Amount would be no less than \$47 million and no more than \$66 million. In addition, concurrently with the payment of the Deposit Amount and closing of the Asset Sale, (i) Cardinal Health 414 posted a \$7 million letter of credit in favor of CRG (at the Company’s cost and expense to be deducted from the closing proceeds due to the Company, and subject to Cardinal Health 414’s indemnification rights under the Purchase Agreement) as security for the amount by which the High Payoff Amount exceeds the Deposit Amount in the event the Company is unable to pay all or a portion of such amount, and (ii) CRG posted a \$12 million letter of credit in favor of the Company as security for the amount by which the Deposit Amount exceeds the Low Payoff Amount. If, on the one hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents exceeds the Deposit Amount, the Company will pay such excess amount, plus the costs incurred by CRG in obtaining CRG’s letter of credit, to CRG and if, on the other hand, it is finally determined by the Texas Court that the amount the Company owes to CRG under the Loan Documents is less than the Deposit Amount, CRG will pay such difference to the Company and reimburse Cardinal Health 414 for the costs incurred by Cardinal Health 414 in obtaining its letter of credit. Any payments owing to CRG arising from a final determination that the Final Payoff Amount is in excess of \$59 million shall first be paid by the Company without resort to the letter of credit posted by Cardinal Health 414, and such letter of credit shall only be a secondary resource in the event of failure of the Company to make payment to CRG. The Company will indemnify Cardinal Health 414 for any costs it incurs in payment to CRG under the settlement, and the Company and Cardinal Health 414 further agree that Cardinal Health 414 can pursue all possible remedies, including offset against earnout payments (guaranteed or otherwise) under the Purchase Agreement, warrant exercise, or any other payments owed by Cardinal Health 414, or any of its affiliates, to the Company, or any of its affiliates, if Cardinal Health 414 incurs any cost associated with payment to CRG under the settlement. The \$2 million being held in escrow pursuant to court order in the Ohio case and the \$3 million being held in escrow pursuant to court order in the Texas case were released to the Company at closing of the Asset Sale. The Texas hearing is currently set for July 3, 2017.

Former CEO Arbitration

On May 12, 2016 the Company received a demand for arbitration through the American Arbitration Association, Columbus, Ohio, from Ricardo J. Gonzalez, the Company’s then Chief Executive Officer, claiming that he was terminated without cause and, alternatively, that he resigned in accordance with Section 4G of his Employment Agreement pursuant to a notice received by the Company on May 9, 2016. On May 13, 2016, the Company notified Mr. Gonzalez that his failure to undertake responsibilities assigned to him by the Board of Directors and otherwise work after being ordered to do so on multiple occasions constituted an effective resignation, and the Company accepted that resignation. The Company rejected the resignation of Mr. Gonzalez pursuant to Section 4G of his Employment Agreement. Also, the Company notified Mr. Gonzalez that, alternatively, his failure to return to work after the expiration of the cure period provided in his Employment Agreement constituted cause for his termination under his Employment Agreement. Mr. Gonzalez is seeking severance and other amounts claimed to be owed to him under his Employment Agreement. In addition, the Company filed counterclaims against Mr. Gonzalez alleging malfeasance by Mr. Gonzalez in his role as Chief Executive Officer. Mr. Gonzalez has withdrawn his claim for additional severance pursuant to Section 4G of his Employment Agreement, and the Company has withdrawn its counterclaims. An arbitration hearing took place April 3-4, 2017 in Columbus, Ohio, and we are currently awaiting a decision.

FTI Consulting, Inc. Litigation

On October 11, 2016, FTI Consulting, Inc. ("FTI") commenced an action against the Company in the Supreme Court of the State of New York, County of New York, seeking damages in excess of \$782,600 comprised of: (i) \$730,264 for investigative and consulting services FTI alleges to have provided to the Company pursuant to an Engagement Agreement, and (ii) in excess of \$52,337 for purported interest due on unpaid invoices, plus attorneys' fees, costs and expenses. On November 14, 2016, the Company filed an Answer and Counterclaim denying the allegations of the Complaint and seeking damages on its Counterclaim, in an amount to be determined at trial, for intentional overbilling by FTI. On February 7, 2017, a preliminary conference was held by the Court at which time a scheduling order governing discovery was issued. The Court set August 31, 2017 as the deadline for FTI to file a Note of Issue and Certificate of Readiness for trial. The Company intends to vigorously defend the action.

Sinotau Litigation – Tc 99m Tilmanocept

On February 1, 2017, Navidea filed suit against Sinotau in the U.S. District Court for the Southern District of Ohio. The Company's complaint included claims seeking a declaration of the rights and obligations of the parties to an agreement regarding rights for the Tc 99m tilmanocept product in China and other claims. The complaint sought a temporary restraining order ("TRO") and preliminary injunction to prevent Sinotau from interfering with the Company's Asset Sale to Cardinal Health 414. On February 3, 2017, the Court granted the TRO and extended it until March 6, 2017. The Asset Sale closed on March 3, 2017. On March 6, the Court dissolved the TRO as moot. The Ohio case remains open because all issues raised in the complaint have not been resolved.

Sinotau also filed a suit against the Company and Cardinal Health 414 in the U.S. District Court for the District of Delaware on February 2, 2017. On February 18, 2017, the Company and Cardinal Health 414 moved to stay the case pending the outcome of the Ohio case. The Court granted the motion on March 1, 2017, and the stay remains in effect.

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, 2016 (the Form 10-K), filed with the SEC on March 31, 2017.

Item 5. Other Information

On May 4, 2017, the Company appointed Jed A. Latkin as its Chief Operating Officer and Chief Financial Officer, which positions were until that date held by Mr. Latkin on an interim basis. In connection with his appointment, the Company entered into an employment agreement with Mr. Latkin. The employment agreement has a one-year term (the "Term"), renewable annually by the board of directors. During the Term, Mr. Latkin will receive an annual base salary of \$325,000. Mr. Latkin shall also be entitled to an annual bonus of up to 75% of his then annual base salary, based on achievement of annual target performance goals established by the compensation committee. In the event that the market capitalization of the Company at the end of the calendar year during the Term is at least \$250,000,000, then the compensation committee of the Board may at its sole discretion increase the annual bonus to an amount equal to up to 100% of his annual base salary. Pursuant to the employment agreement, Mr. Latkin has been granted options to purchase up to 1,000,000 shares of the Company's common stock, \$0.001 par value, that vest as follows: 333,334 option shares with an exercise price of \$0.65 per share are exercisable so long as the closing market price of the underlying common stock equals or exceeds \$0.85 per share; 333,333 option shares with an exercise price of \$0.75 per share will be exercisable on or after December 31, 2017, so long as the closing market price of the underlying common stock equals or exceeds \$1.00 per share; and 333,333 option shares with an exercise price of \$1.00 per share will be exercisable on or after December 31, 2018, so long as the closing market price of the underlying common stock equals or exceeds \$1.25 per share. Mr. Latkin is also entitled to receive his pro rate share of any spin-out subsidiary of the Company as described in his employment agreement.

If, during the Term, the Company terminates Mr. Latkin's employment Without Cause or if he terminates his employment for Good Reason (each as defined in the employment agreement), Mr. Latkin shall be paid as severance his continued base salary, as in effect at termination, payable through the Severance Period (as defined in the Employment Agreement) plus an additional two (2) months' base salary for every completed year of his service. In addition, all stock options granted pursuant to his employment agreement shall vest immediately and remain exercisable through the Severance Period. In lieu of the forgoing severance, if there is a Change of Control (as defined in the employment agreement) during the Term and within six months thereafter Mr. Latkin's employment is terminated either by the Company without Cause (as defined in the employment agreement), by the expiration of the Term, or by Mr. Latkin for Good Reason, Mr. Latkin shall be paid as severance (i) his continued base salary, as in effect at termination, payable through the Severance Period, (ii) a bonus equal to one year of his then current annual base salary plus an additional two (2) months' base salary for every completed year of his service, (iii) his unpaid bonus, if any, for the year he was terminated, prorated to the date of termination, and (iv) the stock options granted pursuant to his employment agreement shall immediately vest.

The Employment Agreement also contains customary non-competition and non-solicitation covenants that bind Mr. Latkin during the Term and for a period of one year thereafter.

Item 6. Exhibits

- 10.1 Global Settlement Agreement dated March 3, 2017 by and among Navidea Biopharmaceuticals, Inc., Cardinal Health 414, LLC, Macrophage Therapeutics, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II (Cayman), L.P., Capital Royalty Partners II – Parallel Fund “A” L.P., Parallel Investment Opportunities Partners II L.P. and Capital Royalty Partners II – Parallel Fund “B” (Cayman) L.P. (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed March 8, 2017).
- 10.2 License-Back Agreement, dated March 3, 2017, between Navidea Biopharmaceuticals, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.3 to the Company’s Current Report on Form 8-K filed March 8, 2017).
- 10.3 Warrant, dated March 3, 2017, issued to Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.4 to the Company’s Current Report on Form 8-K filed March 8, 2017).
- 10.4 Warrant, dated March 3, 2017, issued to The Regents of the University of California (San Diego) (incorporated by reference to Exhibit 10.5 to the Company’s Current Report on Form 8-K filed March 8, 2017).
- 10.5 Amended and Restated License Agreement, dated March 3, 2017, between Navidea Biopharmaceuticals, Inc. and The Regents of the University of California (San Diego) (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission) (incorporated by reference to Exhibit 10.6 to the Company’s Current Report on Form 8-K filed March 8, 2017).
- 10.6 Employment Agreement dated May 4, 2017, by and between Navidea Biopharmaceuticals, Inc. and Jed A. Latkin.*
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
- 31.2 Certification of Chief Operating Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
- 32.1 Certification of Chief Executive Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
- 32.2 Certification of Chief Operating Officer and Chief Financial Officer of Periodic Financial Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.**
- 101.INS 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 and 4 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 10, 2017

By: /s/ Jed A. Latkin

Jed A. Latkin
Chief Operating Officer and Chief Financial Officer
(authorized officer; financial and accounting officer)

INDEX TO EXHIBITS

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* Filed herewith.

** Furnished herewith.

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") is made and entered into effective as of May 4, 2017 (the "Effective Date") by and between **Navidea Biopharmaceuticals, Inc.**, a Delaware corporation with a place of business at 5600 Blazer Parkway, Suite 200, Dublin, Ohio 43017-7550 (the "Company" or "Navidea") and **Jed A Latkin**, residing at 340 West 86th Street Apt 6B, New York, NY 10024 (the "Executive"). The Company and Executive are hereinafter sometimes collectively referred to as the "Parties."

WHEREAS, the Company has offered to employ Executive as its COO and CFO, and the Executive desires to accept such employment; and

WHEREAS, the Parties wish to establish terms, covenants, and conditions for the Executive's employment with the Company through this Employment Agreement (this "Agreement").

NOW, THEREFORE, in consideration of the mutual agreements herein set forth, the Parties agree as follows:

1. Duties. From and after the Effective Date, and based upon the terms and conditions set forth herein, the Company agrees to employ the Executive and the Executive agrees to be employed by the Company, as the Company's COO and CFO and in such additional executive level position or positions as shall be assigned to him by the Company's Board of Directors (the "Board"). While serving in such executive level position or positions, the Executive shall report to, be responsible to, and shall take direction from the Chief Executive Officer. The Executive shall, if requested, also serve as a member of Board or as an officer or director of any affiliate of the Company for no additional compensation. During the Term (as defined in Section 2 below), the Executive agrees to devote substantially all of his working time to the position he holds with the Company and to faithfully, industriously, and to the best of his ability, experience and talent, perform the duties that are assigned to him. The Executive shall also observe and abide by the reasonable corporate policies and decisions of the Company in all business matters.

The Executive represents and warrants to the Company that Exhibit A attached hereto sets forth a true and complete list of (a) all offices, directorships and other positions held by the Executive in corporations and firms other than the Company and its subsidiaries, and (b) any investment or ownership interest in any corporation or firm other than the Company beneficially owned by the Executive (excluding investments in life insurance policies, bank deposits, publicly traded securities that are less than five percent (5%) of their class and real estate). The Executive will promptly notify the Board of any additional positions undertaken or investments made by the Executive during the Term if they are of a type which, if they had existed on the date hereof, should have been listed on Exhibit A hereto. As long as the Executive's other positions or investments in other firms do not create a conflict of interest, violate the Executive's obligations under Section 6 below or cause the Executive to neglect his duties hereunder, such activities and positions shall not be deemed to be a breach of this Agreement.

2. Term of this Agreement. Subject to Section 4 hereof, the term of this Agreement shall be for a period commencing on May 4, 2017 and be automatically renewing every year (the "Term"), unless terminated earlier pursuant to the termination provisions set forth in Section 4 of this Agreement. The Term will be renewable annually with the approval of the Board of Directors and the Executive shall be given at least 30 days notice prior to the yearly renewal date if the contract will not be renewed, in which case Executive shall not be entitled to salary or benefits for the following year.

3. Compensation. During the Term, the Company shall pay, and the Executive agrees to accept as full consideration for the services to be rendered by the Executive hereunder, compensation consisting of the following:

- A. **Salary.** The Company shall pay the Executive a salary of Three Hundred Twenty Five Thousand Dollars (\$325,000) per year (the “Base Salary”).
- B. **Bonus.** For each complete calendar year of the Term, the Executive shall have the opportunity to earn an annual bonus (the “Annual Bonus”) of up to 75% of Base Salary, as in effect at the beginning of the applicable calendar year during the Term, based on achievement of annual target performance goals established by the Committee; provided, however, in the event the market capitalization of the Company at the end of any calendar year during the Term is at least \$250,000,000, then the Committee may **at its sole discretion** increase the Annual Bonus to an amount equal to up to 100% of Base Salary as in effect at the beginning of the applicable calendar year during the Term. The Committee will, on an annual basis, review the performance of the Company and of the Executive in relation to the target performance goals and will pay such Annual Bonus, as it deems appropriate, in its discretion, to the Executive based upon such review. Any bonus earned in any calendar year will be paid on or before March 15th of the year following the year such bonus is earned. In order to be eligible to receive an Annual Bonus, the Executive must be employed by the Company on the last day of the applicable calendar year with respect to which the Annual Bonus is to be paid.
- C. **Benefits.** During the Term, the Executive will receive such employee benefits as are generally available to all executives and officers of the Company.
- D. **Stock Options.**
- i. The Committee may, from time to time, grant to the Executive stock options, restricted stock purchase opportunities and such other forms of equity-based incentive compensation as it deems appropriate, in its discretion. On the date of this Agreement, the Committee will grant Executive non-statutory stock options to purchase 1,000,000 shares of the Company’s common stock, \$0.001 par value (“Common Stock”), at the following values as of the Execution date with a vesting schedule as follows: 333,334 at Execution Date with a strike price of \$0.65 and an exercise right not below \$0.85, 333,333 on December 31, 2017 with a strike price of \$0.75 and an exercise price not below \$1.00, and 333,333 on December 31, 2018 with a strike price of \$1.00 and an exercise right not below \$1.25. All awards of equity incentives shall be governed by a separate equity incentive award agreement, the terms of which shall govern the rights of the Executive and the Company in the event of any conflict between such agreement and this Agreement.
 - ii. Executive shall receive pro-rata any shares of any spin-out subsidiary of Navidea as if his options have fully vested at the time of the proposed spin-out.
- E. **Vacation.** The Executive shall be entitled to twenty-five (25) days of vacation during each calendar year (prorated for partial years) during the Term, in accordance with the Company's vacation policies, as in effect from time to time.
- F. **Expenses.** The Company shall reimburse the Executive for all reasonable out-of-pocket expenses incurred by him in the performance of his duties hereunder, including expenses for travel, entertainment and similar items, promptly after the presentation by the Executive, from time-to-time, of an itemized account of such expenses.
- G. **Clawback Policy.** The Company’s obligation to pay any bonus or stock-based incentive compensation under paragraphs B. or D. of this Section 3, and the Executive’s right to receive or retain such compensation, shall be subject to any policy adopted by the Board of Directors or the Committee (or any successor committee of the Board with authority over executive compensation) pursuant to the “clawback” provisions of Section 304 of the Sarbanes-Oxley Act of 2002, Section 10D of the Securities Exchange Act of 1934 (the “Exchange Act”) or regulations promulgated thereunder, or pursuant to any rule of any national securities exchange on which the equity securities of the Company are listed implementing Section 10D of the Exchange Act or regulations promulgated thereunder.
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4. Termination.

- A. **For Cause.** The Company may terminate the employment of the Executive prior to the end of the Term “for cause.” Termination “for cause” shall be defined as a termination by the Company of the employment of the Executive occasioned by:
- i. the failure by the Executive to cure a willful breach of a material duty imposed on the Executive under this Agreement or any other written agreement between Executive and the Company within 15 days after written notice thereof by the Company;
 - ii. the continuation by the Executive after written notice by the Company of a willful and continued neglect of a duty imposed on the Executive under this Agreement;
 - iii. acts by Executive of fraud, embezzlement, theft or other material dishonesty directed against Navidea;
 - iv. the Executive is formally charged with a felony (other than a traffic offense), or a crime involving moral turpitude, that in the reasonable good faith judgment of the Board, results in material damage to the Company or its reputation, or would materially interfere with the performance of Executive’s obligations under this Agreement; or
 - v. any condition which either results from the Executive’s substantial dependence, as reasonably determined in good faith by the Board, on alcohol, or on any narcotic drug or other controlled or illegal substance.
 - vi. Neglect or dereliction of duties by the Executive or failure to rectify specific performance deficiencies identified by the Company in writing in a performance review within sixty (60) days.

In the event of termination by the Company “for cause,” all salary, benefits and other payments shall cease at the time of termination, and the Company shall have no further obligations to the Executive.

- B. **Resignation.** If the Executive resigns for any reason (other than Good Reason (as defined in paragraph G of this Section 4 below)), all salary, benefits and other payments (except as otherwise provided in paragraph G of this Section 4) shall cease at the time such resignation becomes effective. At the time of any such resignation, the Company shall pay the Executive the value of any accrued but unused vacation time, and the amount of all accrued but previously unpaid Base Salary through the date of such termination. The Company shall promptly reimburse the Executive for the amount of any expenses incurred prior to such termination by the Executive as required under paragraph F of Section 3 above.
- C. **Disability, Death.** The Company may terminate the employment of the Executive prior to the end of the Term if the Executive has been unable to perform his duties hereunder or a similar job for a continuous period of six (6) months due to a physical or mental condition that, in the opinion of a licensed physician, will be of indefinite duration or is without a reasonable probability of recovery for a period of at least six (6) months. The Executive agrees to submit to an examination by a licensed physician of his choice in order to obtain such opinion, at the request of the Company, made after the Executive has been absent from his place of employment for at least six (6) months. The Company shall pay for any requested examination. However, this provision does not abrogate either the Company’s or the Executive’s rights and obligations pursuant to the Family and Medical Leave Act of 1993, and a termination of employment under this paragraph C shall not be deemed to be a termination “for cause.”
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If during the Term, the Executive dies or the Executive's employment is terminated because of the Executive's disability, all salary, benefits and other payments shall cease at the time of death or termination due to disability, provided, however, that the Company shall pay such other amounts or provide such other benefits required to be paid or provided to the Executive or the Executive's estate under any plan, program, policy, practice, contract, or arrangement in which the Executive or the Executive's estate is eligible to receive such payments or benefits from the Company, for the longer of twelve (12) months after such death or termination or the full unexpired Term on the same terms and conditions (including cost) as were applicable before such death or termination. In addition, for the first six (6) months of any disability, as defined under Section 409A of the Internal Revenue Code of 1986, as amended, and any guidance thereunder, that results in the Executive being unable to perform any gainful activity, the Company shall pay to the Executive the difference, if any, between any cash benefits received by the Executive from a Company-sponsored disability insurance policy and the Executive's salary hereunder in accordance with paragraph A of Section 3 above. At the time of any such termination, the Company shall pay the Executive or Executive's estate, the value of any accrued but unused vacation time, and the amount of all accrued but previously unpaid Base Salary through the date of such termination. The Company shall promptly reimburse the Executive or Executive's estate for the amount of any expenses incurred prior to such termination by the Executive as required under paragraph F of Section 3 above.

Notwithstanding the foregoing, if the Company reasonably determines that any of the benefits described in this paragraph C may not be exempt from federal income tax, then for a period of six (6) months after the date of the Executive's termination, the Executive shall pay to the Company an amount equal to the stated taxable cost of such coverages. After the expiration of the six-month period, the Executive or Executive's estate shall receive from the Company a reimbursement of the amounts paid by the Executive.

- D. **Termination Without Cause or by Executive for Good Reason.** A termination "without cause" is a termination of the employment of the Executive by the Company that is not "for cause" and not occasioned by the resignation, death or disability of the Executive. If the Executive's employment is terminated by the Company without cause or by the Executive for Good Reason (whether before the end of the Term or, if the Executive is employed by the Company under paragraph E of this Section 4, after the Term), the Company shall, at the time of such termination, pay to the Executive the severance payment provided in paragraph F of this Section 4 together with the value of any accrued but unused vacation time and the amount of all accrued but previously unpaid Base Salary through the date of such termination and shall provide him with all benefits to which he is entitled under paragraph C of Section 3 above for the duration of the Severance Period (as defined below). Furthermore all share options listed in section 3(D) shall vest immediately and the Executive shall have the right for six months (6) post the Termination date to exercise such share options. The Company shall promptly reimburse the Executive for the amount of any expenses incurred prior to such termination by the Executive as required under paragraph F of Section 3.

If the Company terminates the employment of the Executive because it has ceased to do business or substantially completed the liquidation of its assets or because it has relocated to another city and the Executive has decided not to relocate also, such termination of employment shall be deemed to be without cause.

- E. **End of the Term of this Agreement.** Except as otherwise provided in paragraphs F and G of this Section 4 below, the Company may terminate the employment of the Executive at the end of the Term without any liability on the part of the Company to the Executive, provided that if the Executive continues to be an employee of the Company after the Term ends, his employment shall be governed by the terms and conditions of this Agreement, but he shall be an employee at will and his employment may be terminated at any time by either the Company or the Executive without notice and for any reason not prohibited by law or no reason at all. If the Company terminates the employment of the Executive at the end of the Term, the Company shall, at the time of such termination, pay to the Executive the value of any accrued but unused vacation time and the amount of all accrued but previously unpaid base salary through the date of such termination. The Company shall promptly reimburse the Executive for the amount of any reasonable expenses incurred prior to such termination by the Executive as required under paragraph F of Section 3 above.
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- F. **Severance.** If the employment of the Executive is terminated by the Company not for cause as defined in Section 4 (A), except as per the right to not renew the contract at the end of term, or if the employment of the Executive is terminated by the Company without cause or by the Executive for Good Reason (whether before the end of the Term or, if the Executive is employed by the Company under paragraph E of this Section 4 above, after the Term has ended), then, subject to Executive's execution and non-revocation of a general release in favor of the Company, its affiliates and their current and former officers, directors and employees, in form reasonably satisfactory to the Company, the Executive shall be paid, as severance, (i) Executive's Base Salary, as in effect at the time of such termination, during the Severance Period as if the Executive had not been terminated and remained an employee of the Company through the expiration of such period representing the remainder of his term, and all unvested stock options under section 3(D) shall vest immediately and remain exercisable for the Severance Period. For purposes of this Agreement, "Severance Period" means the period of time commencing immediately after Executive's separation of service from the Company through the date that is twelve (12) months following such separation date, plus an additional two (2) months for every fully completed year of Executive's service to the Company.
- G. **Change of Control Severance.** In addition to the rights of the Executive under the Company's employee benefit plans (paragraph C of Section 3 above) but in lieu of any severance payment under paragraph F of this Section 4 above, if there is a Change in Control of the Company (as defined below) during the Term and within six (6) months thereafter the employment of the Executive is concurrently or subsequently terminated (i) by the Company without cause, (ii) by the expiration of the Term, or (iii) by the resignation of the Executive because he has reasonably determined in good faith that his titles, authorities, responsibilities, salary, bonus opportunities or benefits have been materially diminished, that a material adverse change in his working conditions has occurred, or the Company has breached this Agreement (clause (iii) of the first paragraph of this Section 4(G) shall mean "Good Reason"), the Company shall pay the Executive, as a severance payment, at the time of such termination, in an amount equal to (A) Executive's Base Salary, as in effect at the time of such termination, during the Severance Period as if the Executive had not been terminated and remained an employee of the Company through the expiration of such period, (B) a bonus equal to one (1) year of Base Salary (as in effect on the date of termination) *plus* an additional two months of Base Salary for every fully completed year of Executive's service to the Company payable in equal bi-monthly installments during the Severance Period, and one (1) year of Bonus (as maximum allowable in effect on the date of termination) *plus* an additional two months of prorated bonus for every fully completed year of Executive's service to the Company payable in equal bi-monthly installments during the Severance Period, (C) without duplication to (B), the unpaid bonus, if any, for the year in which the termination occurs, prorated to the date of termination of Executive's employment, to be paid at the time the Company pays bonuses to other senior executives of the Company and (D) the remaining unvested stock options from 3(D) shall vest immediately. The Company shall promptly reimburse the Executive for the amount of any expenses incurred prior to such termination of the Executive as required under paragraph F of Section 3 above. Notwithstanding the foregoing, before the Executive may resign pursuant to clause (iii) of this paragraph, the Executive shall deliver to the Company a written notice of the Executive's intent to terminate his employment thereunder, and the Company shall have been given a reasonable opportunity to cure any such act, omission or condition within thirty (30) days after the Company's receipt of such notice.
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For the purpose of this Agreement, a Change in Control of the Company has occurred when: (a) any person (defined for the purposes of this paragraph G to mean any person within the meaning of Section 13(d) of the Exchange Act), other than Navidea, an employee benefit plan created by its Board of Directors for the benefit of its employees, or a participant in a transaction approved by its Board for the principal purpose of raising additional capital, either directly or indirectly, or an Affiliate of such participant, acquires beneficial ownership (determined under Rule 13d-3 of the regulations promulgated under Section 13(d) of the Exchange Act) of securities issued by Navidea having thirty percent (30%) or more of the voting power of all the voting securities issued by Navidea in the election of directors at the next meeting of the holders of voting securities to be held for such purpose; (b) a majority of the directors elected at any meeting of the holders of voting securities of Navidea are persons who were not nominated for such election by the Board or a duly constituted committee of the Board having authority in such matters; (c) the stockholders of Navidea approve a merger or consolidation of Navidea with another person other than a merger or consolidation in which the holders of Navidea's voting securities issued and outstanding immediately before such merger or consolidation continue to hold voting securities in the surviving or resulting corporation (in the same relative proportions to each other as existed before such event) comprising eighty percent (80%) or more of the voting power for all purposes of the surviving or resulting corporation; or (d) the stockholders of Navidea approve a transfer of substantially all of the assets of Navidea to another person other than: (i) a transfer to a transferee, eighty percent (80%) or more of the voting power of which is owned or controlled by Navidea or by the holders of Navidea's voting securities issued and outstanding immediately before such transfer in the same relative proportions to each other as existed before such event, or (ii) a transfer following which Navidea continues the operation of one or more lines of business that were operated by Navidea prior to the transfer, and a class of Navidea's common stock remains registered under Section 12 of the Exchange Act. The Parties agree that for the purpose of determining the time when a Change of Control has occurred that if any transaction results from a definite proposal that was made before the end of the Term but which continued until after the end of the Term and such transaction is consummated after the end of the Term, such transaction shall be deemed to have occurred when the definite proposal was made for the purposes of the first sentence of this paragraph G of Section 4. Notwithstanding the foregoing, before the Executive may resign pursuant to clause (iii) of the first paragraph of this Section 4(G), the Executive shall deliver to the Company a written notice of the Executive's intent to terminate his employment thereunder, and the Company shall have been given a reasonable opportunity to cure any such act, omission or condition within thirty (30) days after the Company's receipt of such notice.

- H. **Benefit and Stock Plans.** In the event that a benefit plan, equity plan or award agreement which covers the Executive has specific provisions concerning termination of employment, or the death or disability of an employee (*e.g.*, life insurance or disability insurance), then such benefit plan, equity plan or award agreement shall control the disposition of the benefits or awards thereunder.
- I. **Resignation of All Other Positions.** Upon termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the Board (and any committee thereof) of the Company or any of its affiliates.
- J. **Cooperation.** The Parties agree that certain matters in which the Executive will be involved during the Term may necessitate the Executive's cooperation following termination of his employment. Accordingly, following the termination of the Executive's employment for any reason, to the extent reasonably requested by the Board, the Executive shall cooperate with the Company in connection with matters arising out of the Executive's service to the Company; provided that, the Company shall make reasonable efforts to minimize disruption of the Executive's other activities. The Company shall reimburse the Executive for reasonable expenses incurred in connection with such cooperation and, to the extent that the Executive is required to spend substantial time on such matters, the Company shall compensate the Executive at an hourly rate based on the Executive's Base Salary on the date of termination.
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5. **Proprietary Information Agreement.** Executive has executed a Proprietary Information Agreement as a condition of employment with the Company. The Proprietary Information Agreement shall not be limited by this Agreement in any manner, and the Executive shall act in accordance with the provisions of the Proprietary Information Agreement at all times during the Term.
6. **Non-Competition.** Executive agrees that for so long as he is employed by the Company under this Agreement and for one (1) year thereafter, the Executive will not:
- A. enter into the employ of or render any services to any person, firm, or corporation, which is engaged, in any part, in a Competitive Business (as defined below);
 - B. engage in any directly Competitive Business for his own account;
 - C. become associated with or interested in through retention or by employment any Competitive Business as an individual, partner, shareholder, creditor, director, officer, principal, agent, employee, trustee, consultant, advisor, or in any other relationship or capacity; or
 - D. solicit, interfere with, or endeavor to entice away from the Company, any of its customers, strategic partners, or sources of supply.

Nothing in this Agreement shall preclude Executive from taking employment in the banking or related financial services industries nor from investing his personal assets in the securities or any Competitive Business if such securities are traded on a national stock exchange or in the over-the-counter market and if such investment does not result in his beneficially owning, at any time, more than one percent (1%) of the publicly-traded equity securities of such Competitive Business. "Competitive Business" for purposes of this Agreement shall mean any business or enterprise:

- a. which is engaged in the development, commercialization or distribution of drugs and/or systems for use in detection, diagnosis or treatment of cancer, inflammatory or immune-related diseases, including without limitation the development, commercialization or distribution of radiopharmaceuticals for such purposes, or
- b. which reasonably could be understood to be competitive in the relevant market with products and/or systems described in clause *a* above, or
- c. in which the Company engages in during the Term pursuant to a determination of the Board and from which the Company derives a material amount of revenue or in which the Company has made a material capital investment.

The covenant set forth in this Section 6 shall terminate immediately upon the substantial completion of the liquidation of assets of the Company or the termination of the employment of the Executive by the Company without cause or at the end of the Term.

7. **Arbitration.** Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in Columbus, Ohio, in accordance with the non-union employment arbitration rules of the American Arbitration Association ("AAA") then in effect. If specific non-union employment dispute rules are not in effect, then AAA commercial arbitration rules shall govern the dispute. If the amount claimed exceeds \$100,000, the arbitration shall be before a panel of three arbitrators. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall indemnify the Executive against and hold him harmless from any attorney's fees, court costs and other expenses incurred by the Executive in connection with the preparation, commencement, prosecution, defense, or enforcement of any arbitration, award, confirmation or judgment in order to assert or defend any right or obtain any payment under paragraph C of Section 4 above or under this sentence; without regard to the success of the Executive or his attorney in any such arbitration or proceeding.
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8. **Attorneys' Fees and Expenses** . Except as otherwise provided in Section 7, in the event that any action, suit, or other legal or equitable proceeding is brought by either party to enforce the provisions of this Agreement, or to obtain money damages for the breach thereof, then the party which substantially prevails in such action (whether by judgment or settlement) shall be entitled to recover from the other party all reasonable expenses of such litigation (including any appeals), including, but not limited to, reasonable attorneys' fees and disbursements.
 9. **Governing Law**. The Agreement shall be governed by and construed in accordance with the laws of the State of Ohio without regard to its conflicts of laws principles.
 10. **Jurisdiction; Service of Process**. Except as otherwise provided in Section 7, any action or proceeding arising out of or relating to this Agreement shall be brought exclusively in the state or federal courts located in New York, New York and each of the Parties irrevocably submits to the jurisdiction of each such court in any such action or proceeding, waives any objection it may now or hereafter have to venue or to convenience of forum, agrees that all claims in respect of the action or proceeding shall be heard and determined only in any such court and agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court. The Parties agree that either or both of them may file a copy of this Section with any court as written evidence of the knowing, voluntary and bargained agreement between the Parties irrevocably to waive any objections to venue or to convenience of forum. Process in any action or proceeding referred to in the first sentence of this section may be served on any party anywhere in the world
 11. **Waiver of Jury Trial** . THE PARTIES HEREBY UNCONDITIONALLY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING DIRECTLY OR INDIRECTLY OUT OF, RELATED TO, OR IN ANY WAY CONNECTED WITH THE PERFORMANCE OR BREACH OF THIS AGREEMENT, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED BETWEEN THEM. The scope of this waiver is intended to be all encompassing of any and all disputes that may be filed in any court or other tribunal (including, without limitation, contract claims, tort claims, breach of duty claims, and all other common law and statutory claims). THIS WAIVER IS IRREVOCABLE, MEANING THAT IT MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING, AND THE WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS, OR MODIFICATIONS TO THIS AGREEMENT AND RELATED DOCUMENTS. In the event of litigation, this Agreement may be filed as a written consent to a trial by the court.
 12. **Validity**. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of the Agreement, which shall remain in full force and effect.
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13. **Compliance with Section 409A of the Internal Revenue Code.** It is intended that this Agreement comply with Section 409A of the Internal Revenue Code of 1986, as amended, and any guidance thereunder ("Section 409A"). If, when the Executive's employment with the Company terminates, the Executive is a "specified employee" as defined in Section 409A(a)(1)(B)(i), and if any payments under this Agreement, including payments under Section 4, will result in additional tax or interest to the Executive under Section 409A(a)(1)(B) ("Section 409A Penalties"), then despite any provision of this Agreement to the contrary, the Executive will not be entitled to payments until the earliest of (a) the date that is at least six months after termination of the Executive's employment for reasons other than the Executive's death, (b) the date of the Executive's death, or (c) any earlier date that does not result in Section 409A Penalties to the Executive. As soon as practicable after the end of the period during which payments are delayed under this provision, the entire amount of the delayed payments shall be paid to the Executive in a lump sum. Additionally, if any provision of this Agreement would subject the Executive to Section 409A Penalties, the Company will apply such provision in a manner consistent with Section 409A during any period in which an arrangement is permitted to comply operationally with Section 409A and before a formal amendment to this Agreement is required. For purposes of this Agreement, any reference to the Executive's termination of employment will mean that the Executive has incurred a "separation from service" under Section 409A. No payments to be made under this Agreement may be accelerated or deferred except as specifically permitted under Section 409A. Any payments that qualify for the "short-term deferral" exception or another exception under Section 409A of the Code shall be paid under the applicable exception. Each payment of compensation under this Agreement shall be treated as a separate payment of compensation for purposes of Section 409A. To the extent that any reimbursements provided under this Agreement constitute deferred compensation subject to Section 409A, such amounts shall be paid or reimbursed to Executive promptly, but in no event later than December 31 of the year following the year in which the expense is incurred. The amount of any such payments eligible for reimbursement in one year shall not affect the payments or expenses that are eligible for payment or reimbursement in any other taxable year, and Executive's right to such payments or reimbursement shall not be subject to liquidation or exchange for any other benefit.
14. **Entire Agreement.** This Agreement, together with the Proprietary Information Agreement referenced above, constitutes the entire understanding between the Parties with respect to the subject matter hereof, and supersedes all negotiations, prior discussions, and preliminary agreements to this Agreement. This Agreement may not be amended except in writing executed by the Parties.
15. **Effect on Successors of Interest.** This Agreement shall inure to the benefit of and be binding upon heirs, administrators, executors, successors and assigns of each of the Parties. Notwithstanding the above, the Executive recognizes and agrees that his obligation under this Agreement may not be assigned without the consent of the Company. The Company, however, may assign its rights and obligations under this Agreement.
16. **Counterpart Signatures.** This Agreement may be signed in counterparts, each of which when so executed and delivered shall be an original, but all such counterparts together shall constitute one and the same instrument. A fully signed copy, pdf or facsimile copy of this Agreement shall be deemed an original.

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed and delivered this Agreement as of the date first written above.

NAVIDEA BIOPHARMACEUTICALS, INC.

EXECUTIVE:

By: /s/ Michael M. Goldberg
Name: Michael M. Goldberg
Its: CEO

/s/ Jed A. Latkin
Jed A. Latkin

Exhibit A

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

I, Michael M. Golberg, certify that:

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

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

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

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

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

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

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

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

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

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

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

May 10, 2017

/s/ Michael M. Goldberg

Michael M. Goldberg, M.D.
President and Chief Executive Officer
(principal executive officer)

**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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

May 10, 2017

/s/ Jed A. Latkin

Jed A. Latkin

Chief Operating Officer and Chief Financial Officer
(principal 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 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 10, 2017

/s/ Michael M. Goldberg

Michael M. Goldberg, M.D.
President and Chief Executive Officer
(principal executive 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 Operating 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 10, 2017

/s/ Jed A. Latkin

Jed A. Latkin

Chief Operating Officer and Chief Financial Officer

(principal financial and accounting officer)
